**RESEARCH PARTICIPANT CONSENT INFORMATION FOR ONLINE SURVEY**

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

**VCU INVESTIGATOR:** [Insert the full name, title, and phone number of the VCU Principal Investigator]

**SPONSOR:** [Insert the full name of the funding sponsor. If there is no sponsor for this research, delete this item]

*TEMPLATE INSTRUCTIONS: This template is based on research study conducting an* ***online survey/questionnaire as the sole research activity*** *participants will be involved in.*If participants will complete multiple research activities, use either the Biomedical or Social-Behavioral Consent Templates.

Refer to either the Biomedical or Social-Behavioral Consent Templates for full instructions about what needs to be in consent forms. Use other template language from these templates as appropriate.

**In order to use this template for expedited and full board studies, you must request a “Waiver of Documentation of Consent” (the consent signature) in the IRB submission. In addition, if you choose not to include all of the required elements in your script, you must request a “Waiver of Certain Elements of Consent” in the IRB submission and list the elements that you want to waive.**

* Instructions and comments are indicated in orange or blue boxes, and [yellow highlighting].
* Delete the instructions and comments after reading and following.
* Required information is indicated in the instruction boxes. You may delete the optional sections and language if they are not applicable to your study.
* Example text should be edited to be appropriate for your study.
* Headings are recommended to facilitate comprehension
* 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, consider replacing “you” with “your child” and “consent” with “parental permission” throughout

*[Include if appropriate:] NOTE: In this consent form, “you” always refers to the research participant. [Include if this study will enroll decisionally impaired subjects:]* *If you are a legally authorized representative, please remember that “you” refers to the study participant. [Include if this study will enroll child subjects:]* *If you are a parent or legal guardian, please remember that “you” refers to the child study participant.*

**ABOUT THIS CONSENT FORM**

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please contact the investigator or the study staff to explain any information in this consent document that is not clear to you.** [Insert if applicable:] You may print a copy of this consent information to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

**WHY IS THIS STUDY BEING DONE?**

[Example 1] The purpose of this research study is to find out about \_\_\_\_. We think that \_\_\_ may help/affect/cause/be related to \_\_\_ by/because \_\_\_\_\_. This study will allow us to learn more about it.

[Example 2] Condition causes symptoms or behaviors, which may involve \_\_\_. [Insert short discussion of how or why the study intervention might affect the condition or behavior. Do not promise efficacy or safety.]

[If conducting the study in a prison setting with research project involving prison staff or inmates as participants, also include a description of the anticipated uses of the results of the research.] The results of this study will be used to \_\_\_.

**WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?**

If you agree to take this [insert length of time] survey, you will be asked questions about [describe all the topics of the questions you will ask]. Approximately [insert how many total] individuals will participate in this study.

**WHAT ALTERNATIVES ARE AVAILABLE?**

[If participants have an alternative way of completing the survey (e.g. filling out a paper survey, doing a phone interview, going to a study location for an in-person interview, etc.), describe that option. Example:] You have the option to take a paper survey instead of completing it online. If you would like to take the paper survey, please contact the study team.

[Example:] You can receive extra credit without being in the study by [explain the alternative way to earn credit].

**WHAT ARE THE BENEFITS OF BEING IN THE STUDY?**

 [Example 1 – potential direct benefits] There is no guarantee that you will receive any benefits from being in this study. However possible benefits include \_\_\_\_. We hope the information learned from this study will provide more information about \_\_\_\_.

[Example 2 – no anticipated direct benefits] This study is not likely to/will not benefit you. However, it may help the investigators understand how \_\_\_\_\_ works.

**WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?**

Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

[Example:] Questionnaires may contain questions that are [sensitive/personal/upsetting/ offensive/disturbing/etc.] in nature. You may refuse to answer any question that makes you feel uncomfortable.

[Example:] This study will ask you questions about personal topics that might be embarrassing to talk about and that could affect your family relationships if this information were to become known outside of the study. You will also be asked about illegal activities, which could have legal and financial consequences if this information were to become known outside of the study.

[Example:] You may learn things about yourself that you did not know before and that could affect how you think about yourself.

[Example of authorized deception risks (withholding information or misleading participants):] During this study, you will be unaware of or misled regarding the nature or purpose of the research. We will tell you at the end of the study what the true nature or purpose of the research is, but you may feel upset or uncomfortable during or after the study.

**HOW WILL INFORMATION ABOUT ME BE PROTECTED?**

INSTRUCTIONS: Include in this section a description of how the study staff will keep research data secure and identify all individuals and groups who may access the data.

**Basic element of consent 46.116(b)(5):** “A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained”

**\*\* This is required information for all studies and modifications are not recommended.**

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information will be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

* The study Sponsor, representatives of the sponsor and other collaborating organizations [delete if there is no Sponsor]
* Representatives of VCU and the VCU Health System/VCU Dental Care
* Officials of the Department of Health and Human Services [insert any other federal funding agencies such as the Departments of Defense, Justice or Education] or the Federal Food and Drug Administration [reference to the FDA may be deleted if this is not an FDA regulated study]
* [If research is conducted in foreign countries include the following statement:] This research is also being conducted in foreign countries, so personal information pertaining to you may be shared or copied by authorized agents of governmental agencies in those countries.

In general, we will not give you any individual results from the study. [Insert if participants will receive aggregate results:] Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.

**\*\*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 edited.**

**Some social-behavioral studies meet the definition of being a clinical trial.** For more information, see <https://cctr.vcu.edu/clinicalresearch/services/clinicaltrialsgov.html> and

<https://cctr.vcu.edu/pdfs/Service_ClinicalTrials.gov_SummaryChart.pdf>

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 anytime.

As employees of an institution of higher education in Virginia, VCU faculty and staff are mandated reporters and are obligated to report child and elder abuse. If there is the potential for any participant to disclose that they may cause injury to themselves or others, you should state in this section that you are required by law to report that information to the appropriate authorities.

Note: When research is supported by the Department of Justice, in order to report child abuse, the researcher must obtain a separate consent to allow child abuse reporting. The National Institute of Justice provides a consent template for this purpose.

**\*\*The following information is required if there is the potential for you to discover suspected child or elder abuse or other conditions that have mandated reporting during the course of the study and may be modified as appropriate.**

[Example:] We will not tell anyone the answers your child gives us. But, if your child tells us that someone is hurting her or him, or that she might hurt herself or someone else, the law says that we must let people in authority know so they can protect your child.

[Example:] If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

**\*\*The following paragraph is required if the study will include prisoners as subjects and modifications are not recommended.**

If you are or should become involuntarily detained, confined or incarcerated (in a jail, prison or alternative facility), you should be aware that confidentiality regarding your status as a prisoner cannot be guaranteed. Personal information about you might be shared with or copied by authorized representatives of the prison facility and/or prison system.

All research involving human participants conducted within the Bureau of Prison system must comply with additional requirements established by the Bureau of Prisons in order to be approved by the IRB. Consent requirements are outlined in 28 CFR 512.16 and the [VCU HRPP Toolkit](https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/).

**\*\*The following information is required if the study is conduct in a prison setting involving prison staff or inmates as participants:**

[Describe any exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself/herself, or, if the subject is an inmate, indicates intent to leave the facility without authorization] If you tell us \_\_\_\_, then we are required to report that information to \_\_\_\_.

All non-exempt research involving human participants supported through a funding award from the Department of Justice (DoJ), including the National Institute of Justice, must comply with additional requirements established by the DoJ in order to be approved by the IRB. Consent requirements are outlined in 26 CFR 46.116 and the [VCU HRPP Toolkit](https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/).

**\*\*The following information is required for all studies funded by the Department of Justice:**

Private, identifiable information will only be used for research and statistical purposes. However, if you indicate future criminal intent, the researchers are required by law to report this to the authorities. [Any other intended disclosures for research purposes must be explicitly identified in the informed consent document including what will be disclosed, under what circumstances, and to whom.] Project findings and reports prepared for dissemination will not contain information which can reasonably be expected to be identifiable. [If findings in a project cannot, by virtue of sample size or uniqueness of subject, be expected to totally conceal subject identity, this must be included in the informed consent.] [If the study is funded by the National Institute of Justice, insert:] At the end of the study, a copy of all the data (without any information that could identify you) will be submitted to the National Archive of Criminal Justice Data.

INSTRUCTIONS: Insert the language of either Option A or Option B. If there is any chance that information could be used in future studies, insert Option A.

**Basic element of consent 46.116(b)(9):** “One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.”

**\*\*The following text is required for all studies with identifiable or de-identified information (i.e. studies that keep a key linking participant IDs with direct identifiers like names) and modifications are not recommended.**

[Option A – Studies that will or might use information for future research studies, insert:] In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

[Option B – Studies that will not use information for future research studies, insert:] The information collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

**\*\*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 edited.**

**Some social-behavioral studies meet the definition of being a clinical trial.** For more information, see <https://cctr.vcu.edu/clinicalresearch/services/clinicaltrialsgov.html> and

<https://cctr.vcu.edu/pdfs/Service_ClinicalTrials.gov_SummaryChart.pdf>

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 anytime.

**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.]

**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.).

**\*\*This is an optional section that applies only to studies accessing, using, or maintaining PHI.**

**Remove this section if a separate HIPAA Authorization form will be used. Modifications are not recommended.** **Modifications are not recommended.**

**In order to use this template for expedited and full board studies, you must request a Partial Waiver of Authorization in the IRB submission.** Request to waive the following 2 elements:

1) the authorization signature and

2) the requirement to provide the subject with a copy of the signed authorization.

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/irb_wpp/XII-3.htm)). A Partial Waiver should be requested for any omitted elements.

As part of this research study, we will ask you to share identifiable health information with us and/or 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 [insert 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 the use of a Data Registry and will expire [specify other expiration date].

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

### 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].

**WHAT ARE THE COSTS?**

INSTRUCTIONS: Include a description of all costs that the participant will be responsible for paying.

**\*\*This is an optional section that applies only to studies where there will be costs to the participant and may be modified as appropriate.**

[Example:] You will be responsible for paying the cost of the minutes used during this telephone call.

**WILL I BE PAID TO PARTICIPATE?**

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 that applies only 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 annually report these payments 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.

**WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?**

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

**[Insert name and two forms of contact information of VCU Principal Investigator.]**

 and/or

**[Insert name and two forms of contact information of additional contact person/people for study]**

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research

800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298

(804) 827-2157; <https://research.vcu.edu/human_research/volunteers.htm>

**If you have any questions, please contact the study team before taking the survey.**

**STATEMENT OF CONSENT [AND/OR PARENT/LEGAL GUARDIAN PERMISSION]**

I have been provided with an opportunity to read this consent form [permission form] carefully. All of the questions that I wish to raise concerning this study have been answered.

Instructions: This consent question should be set up so that if the potential participant selects “No,” then they will not proceed to the survey.

Do you consent [give permission for my child] to participate in this research survey?

YES

NO

*[If providing parental permission:]* Please indicate your relationship to the child: \_\_\_\_\_\_\_\_\_\_\_\_

**OPTIONAL MAINTENANCE OF CONTACT INFORMATION FOR FUTURE STUDIES**

**Studies that plan to keep only contact information to aid in recruitment for other future studies should include this section. If you plan to keep research data as well as contact information, use the next section for registries instead of this one.**

We may have other studies like this one that you might be interested in. With your permission, I would like to keep your name and [describe any other contact information such as address, phone number, e-mail address, etc. being kept by the study] in our research database so that we could contact you when we begin any new studies. This information would not be stored with any of the information you provide in this interview.

Do you give permission for your contact information to be saved and used to contact you about future studies?

YES

NO

**OPTIONAL STORAGE FOR FUTURE RESEARCH STUDIES**

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

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

• The purpose of creating or contributing to a registry

• What data will be stored, where, and by whom

• The potential secondary uses of the data

• Risks of re-identification and potential loss of confidentiality

• Whether/how participants can withdraw their data from the registry.

Additional information about the registry, 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 and may be modified as appropriate 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 data and to the use of their data in any future unspecified research on any topic ("general research use"). Unrestricted consent maximizes the utility of collected data.

Specific consent:

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

To advance science, it is helpful for researchers to share information. They do this by putting data into one or more scientific databases (called registries), 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 that you provide, along with your [describe the identifiers that will be part of the registry (name, phone, email, etc.)] in a registry to be available for other research studies in the future. Your information 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 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.

[Example - Unrestricted consent for sharing] Your information will be stored indefinitely by \_\_\_\_ in one or more scientific databases at \_\_\_\_, and shared with other researchers. The 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.

[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 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 information in research. [Or describe your plan for recontacting the child to obtain consent]

Do you agree that your information may be stored and used for future research as described above?

YES

NO