*[All instructions and comments are in italics and [ ]. Remove these from actual consent document.]*

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

[For use with adult research participants and/or as a permission form for parents to agree to the participation of their child in a research study]

**TITLE:**

**VCU IRB NO.**:

**SPONSOR**: *[if no sponsor for this research, delete this field]*

[This template is designed for use with typical social/behavioral research studies. It should be reworded as necessary to reflect specific circumstances of the research and the research participants. The language used in this template is written at approximately the 8th grade level so that it can be used with individuals who may have limited reading skills. You may adapt the language if you know your participants have a higher or lower reading level. You can check the reading level of your consent form within Word.]

If any information contained in this consent form is not clear, please ask the study staff to explain any information that you do not fully understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

**PURPOSE OF THE STUDY**

*[Briefly fill in purpose of the study].*

*Ex:* The purpose of this research study is to find out about teenagers’ attitudes toward sex and drugs.

[If this document is used for parental permission for a child’s participation in a research study, change all phrases of ‘you are’ to ‘your child is’ and make other adjustments as necessary.]

*[Briefly fill in why this person is in your sample.]*

*Ex:* You are being asked to participate in this study because you have a teenage child that attends Urban Middle School.

## DESCRIPTION OF THE STUDY AND YOUR [YOUR CHILD’S] INVOLVEMENT

If you decide to be in this research study, you will be asked to sign this consent form *[change to* permission form *if parents or legal guardian are agreeing to child’s participation]* after you have had all your questions answered and understand what will happen to you *[your child]*.

*[Describe what participation in this study will entail for participants including how long the study will last and approximately how many participants will participate in this study.] Ex:* In this study you will be asked to attend two group meetings. Each meeting will last approximately one hour. In each meeting, you will be in a group with 8 or 9 other parents. In the first meeting, you will be asked to talk about . . . *[Provide examples of the types of questions you will be asking/content that will be discussed.].* In the second meeting you will be asked to talk about . . . The meetings will be tape recorded so we are sure to get everyone’s ideas, but no names will be recorded on the tape.

*Identify any experimental interventions or interactions including use of randomization.*

Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

**RISKS AND DISCOMFORTS**

*[Possible psychological risks or discomforts must be noted and how they will be handled.]*

*Ex*: Sometimes talking about these subjects causes people to become upset. Several questions will ask about things that have happened in your family that may have been unpleasant. You do not have to talk about any subjects you do not want to talk about, and you may leave the group at any time. If you become upset, the study staff will give you names of counselors to contact so you can get help in dealing with these issues.

**USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION**

*[Remove this entire section if 1) the study does not involve the use or disclosure of protected health information or 2) a separate authorization form will be utilized. Edit the content of this section appropriately. For more information, see the HIPAA for research webpage at* http://www.research.vcu.edu/irb/hipaa-guidance.htm*]*

**Authority to Request Protected Health Information**

The following people and/or groups may request my Protected Health Information:

|  |  |
| --- | --- |
| * Principal Investigator and Research Staff | * Study Sponsor |
| * Research Collaborators | * Institutional Review Boards |
| * Data Safety Monitoring Boards | * Government/Health Agencies |
| * Others as Required by Law |  |

### Authority to Release Protected Health Information

The VCU Health System (VCUHS) may release the information identified in this authorization from my medical records and provide this information to:

|  |  |
| --- | --- |
| * Health Care Providers at the VCUHS | * Principal Investigator and Research Staff |
| * Study Sponsor | * Research Collaborators |
| * Data Coordinators | * Institutional Review Boards |
| * Data Safety Monitoring Boards | * Government/Health Agencies |
| * 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.

**Type of Information that may be Released**

*[This section to be filled-out by the Principal Investigator – double click on the boxes to insert a check]*

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 | X-ray reports | | X-ray films / images |
| Photographs, videotapes | Complete billing record | | Itemized bill |
| Information about drug or alcohol abuse | | Information about Hepatitis B or C tests | |
| Information about psychiatric care | | Information about sexually transmitted diseases | |
| Other (specify): | | | |

**Expiration of This Authorization**

***[****This section to be filled out by the Principal Investigator – double click on the boxes to insert a check]*

|  |
| --- |
| 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. |
| This research study involves the use of a Data or Tissue Repository (bank) and will never expire. |
| Other (specify): |

### Right to Revoke Authorization and Re-disclosure

You may change your mind and revoke (take back) the right to use your protected health information at any time. 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.

**BENEFITS TO YOU AND OTHERS**

*[If there are direct benefits those should be listed, however, most social/behavioral studies do not provide* ***direct*** *benefits to the participants. They may provide some indirect benefits. This should be stated in this section.]*

*Ex:* You may not get any direct benefit from this study, but, the information we learn from people in this study may help us design better programs for parents and schools.

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

**COSTS**

*[Identify any costs to the participants, including their time. Specify if they are receiving a drug or intervention for which there is a cost]*

Ex1: There are no costs for participating in this study other than the time you will spend in the groups and filling out questionnaires.

Ex 2: You will not be charged for the visits to the nurse, and we will pay for you to take the bus or park your car when you come for the study visit.

**PAYMENT FOR PARTICIPATION**

[You only need to have this section if you are paying participants. If you are paying for participation you must be very specific as to the amount and how it will be paid.]

Ex: You will receive a $10.00 gift certificate at a local mall each time you participate in a group session. The $10.00 gift certificate will be given at the end of each session. You may receive a total of $30.00 if you participate in all 3 sessions.

[If payment for this study is substantial and participants could earn more than $600 per year by participating in your study and/or a combination of studies, include the following.]

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.

[*Depending on the type of payment being offered]:*

You may be asked to provide your social security number in order to receive payment for your participation. Your social security number is required by federal law. It will not be included in any information collected about you for this research. Your social security number will be kept confidential and will only be used in order to process payment.

**ALTERNATIVES**

[If this is a treatment study, list alternative treatments, otherwise note that the alternative is to not participate in the study.]

**CONFIDENTIALITY**

Potentially identifiable information about you will consist of *[list e.g., surveys, interview notes and recordings, audiotapes of consultations and interviews, and data abstracted from the medical record]*. Data is being collected only for research purposes.

*[Note how the data will be identified, stored and protected and destroyed. Please review VCU policy, State and sponsor requirements regarding retention of records. As appropriate to this study add information regarding retention in this section]. ]. Ex:* Your data will be identified by ID numbers and birthdates, not names, and stored separately from research data in a locked research area. All personal identifying information will be kept in password protected files and these files will be deleted *[Note time frame]*. Other records *[Note which ones]* will be kept in a locked file cabinet for *[Note time frame]* after the study ends and will be destroyed at that time. *[Note which files]* will be kept indefinitely. Access to all data will be limited to study personnel. A data and safety monitoring plan is established.

[If you are video or audio taping a session you must specify how you will protect the information you are taping.]

Ex: The group sessions will be audio taped, but no names will be recorded. At the beginning of the session, all members will be asked to use initials only so that no names are recorded. The tapes and the notes will be stored in a locked cabinet. After the information from the tapes is typed up, the tapes will be destroyed.

We will not tell anyone the answers you *[your child]* give us; however, information from the study and information from your medical record *[include medical record reference only if appropriate]* and the consent form signed by you may be looked at or copied for research or legal purposes by the sponsor of the research *[only include sponsor if appropriate]*, or by Virginia Commonwealth University. Personal information about you might be shared with or copied by authorized officials of the Department of Health and Human Services or other federal regulatory bodies.

[If there is the potential for you to discover suspected child or elder abuse, as an employee of an institution of higher education in Virginia, you are obligated to report this. Include a statement indicating the requirement to report. 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. 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.] Ex: If, as part of this research, we learn about real or suspected child or elder abuse, the law says that we have to let people in authority know so they can protect the person(s) at risk. OR: If something we learn through this research indicates that you may intend to harm yourself or others, we are obligated to report that to the appropriate authorities.

*[If research is conducted in foreign countries include the following statement:]* If the research is conducted in foreign countries, personal information pertaining to you may be shared or copied by authorized agents of governmental agencies in those countries.

*[If research will have a Certificate of Confidentiality from the NIH, insert the following:]*

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

*[If there may be a need to disclose things such as child abuse, intent to hurt self or others, include language such as the following.]* The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. [State here the conditions under which disclosure would be made.]

*[If this study is a clinical trial, the language in this paragraph must be provided in its entirety (required by the FDA). If this study is not a clinical trial, this paragraph should be deleted.]* 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.

What we find from this study may be presented at meetings or published in papers, but your *[your child’s]* name will not ever be used in these presentations or papers.

**DATA REGISTRIES**

*[Consider implementing the following layered levels of consent if a registry is being created or you will be contributing to an existing registry. Layers may not be required, although participants may feel they have more control over their participation. If utilizing these layers, your registry must have provisions for respecting them.]*

1. I give permission for my data/specimens to be stored and used for research related to [*insert topic*]

YES \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NO \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. I give permission for my data/specimens to be stored and used for future research about other health problems.

YES \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NO \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3. I give permission for my data/specimens to be stored; however, I want to be contacted prior to any future use of my data/specimens for research.

YES \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NO \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**GENETIC TESTING**

*[Only need to have if genetic testing is involved.]*

***[For Multi-center protocols (not initiated at VCU)]***

*[Include a description of the research plan with attention to the special concerns raised by genetic testing. (These concerns may be inferred from the section on VCU-initiated protocols below.) Investigators may need to modify the proposed informed consent form in order to provide this information. If participants may make choices concerning the use of their samples, these should be indicated in a check-off format (see below). Investigators should take care, however, that the modified informed consent form reflects that the actual research plan. This may be difficult if the research plan is vague.]*

***[For VCU-initiated protocols, the following issues should be addressed]***

**Background information:** The research involves genetic testing. Genetic testing may reveal information about the likelihood that a person or his or her relatives may develop certain diseases. Genetic testing may reveal information about who is related to whom. If known to employers or insurance companies, the results of genetic testing might affect a person's ability to obtain a job or health or life insurance.

Current and future studies: *[Consider implementing the following layered levels of consent:]*

1. My blood/tissue samples may be stored and used for future research about [*insert topic*].

YES NO

initial initial

1. My blood/tissue samples may be stored and used for future research about other health problems (for example, heart disease, osteoporosis, diabetes, etc.)

YES NO

initial initial

**Future contact concerning further genetic testing research:** *[Describe the circumstances under which participants might be contacted in the future concerning further participation in this or related genetic testing research. Consider offering the participant the option of opting out of such contacts at this time with a Yes/No response to a question formatted like those above.]*

**Future contact concerning genetic testing results:** *[If planned or possible future genetic testing results are unlikely to have clinical implications, then a statement that the results will not be made available to participants may be appropriate. If results might be of clinical significance, then describe the circumstances and procedures by which participants would receive results. Describe how participants might access genetic counseling for assistance in understanding the implications of genetic testing results, and whether this might involve costs to participants. Investigators should be aware that federal regulations, in general, require that testing results used in clinical management must have been obtained in a CLIA-certified laboratory.]*

**Withdrawal of genetic testing consent:** *[Describe whether and how participants might in the future request to have test results and/or samples withdrawn in order to prevent further analysis, reporting, and/or testing.]*

**Confidentiality:** *[Describe the extent to which genetic testing r*esults *will remain confidential and special precautions, if any, to protect confidentiality.]*

**IF AN INJURY OR ILLNESS HAPPENS**

*[This element is required for greater than minimal risk research as per §46.116(a)(6) and 21CFR50, as appropriate. It is not required, and generally not appropriate, for expedited research; no waiver of this element needs to be requested]*

If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study.

To help avoid research-related injury or illness it is very important to follow all study directions.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL**

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study. *[If appropriate you may need to include a statement that their decision to withdraw will involve no penalty or loss of care, service or benefits to which they are otherwise entitled from this agency/service provider.]*

Your participation in this study may be stopped at any time by the study staff or the sponsor *[if applicable]* without your consent. The reasons might include:

* the study staff thinks it necessary for your health or safety;
* you have not followed study instructions;
* the sponsor has stopped the study; or
* administrative reasons require your withdrawal.

If you leave the study before the final regularly scheduled visit, *[Insert any consequences of a subject’s decision to withdraw from the research (i.e., psychological risks or discomforts) and procedures for orderly termination of participation by the subject (i.e., follow-up visits with study team).*]

**QUESTIONS**

If you have any questions, complaints, or concerns about your participation in this research, contact:

**[Insert name and contact information of contact person for study]**

and/or

**[Insert name and contact information of additional contact person for study – (optional)]**

[List the name of the contact person and his/her contact information here. The contact person should be a full-time faculty or staff person. More than one contact may be listed. Give name and role of primary contact first. **Use bold type and larger font for names and contact information.**]

The researcher/study staff named above is the best person(s) to call for questions about your participation in this study.

If you have any general questions about your rights as a participant in this or any other research, you may contact:

Office of Research

Virginia Commonwealth University

800 East Leigh Street, Suite 3000

P.O. Box 980568

Richmond, VA 23298

Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk with someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

**CONSENT**

[Change consent to permission if parents or legal guardian are agreeing to child’s participation.]

*I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate* [for my child to participate] *in this study*. *I will receive a copy of the consent form once I have agreed to participate.*

Name of Child [only include this line if needed]

Participant name printed Participant signature Date

***[NOTE: DELETE THE PARENT OR LEGAL GUARDIAN LINES UNLESS THE STUDY ALLOWS FOR THE ENROLLMENT OF CHILDREN]* 1**

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

Name of Parent or Legal Guardian

(Printed)

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

Parent or Legal Guardian Signature Date

***[NOTE: DELETE THE LEGALLY AUTHORIZED REPRESENTATIV LINES UNLESS THE STUDY ALLOWS FOR THE INVOLVEMENT OF ADULTS WHO ARE UNABLE TO PROVIDE CONSENT]* 2**

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

Name of Legally Authorized Representative

(Printed)

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

Legally Authorized Representative Signature Date

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

Name of Person Conducting Informed Consent

Discussion / Witness 3

(Printed)

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

Signature of Person Conducting Informed Consent Date

Discussion / Witness

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

Principal Investigator Signature (if different from above) Date 4

1 *[If the study allows for the involvement of children, the permission of BOTH parents is required for certain categories of research unless one is deceased, unknown, incompetent, or only one parent has legal responsibility for care and custody. The categories of research are: (a) research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition (45.CFR 46.406) or (b) research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of children. (45.CFR 46.407) Include lines for BOTH parents to print their names and lines for BOTH signatures and date if the research involves one of the two categories listed above.]*

2 *[If the study allows for the involvement of adults who are unable to provide consent, the consent of a legally authorized representative is required.]*

3*[A witness to the signature of a research participant is required by VA Code. If the witness is to be someone other than the person conducting the informed consent discussion, include a line for the witness to print his/her name and lines for signature and date.]*

*4 [The purpose of this signature is to ensure that the principal investigator is aware of who has been enrolled in studies. The principal investigator’s signature date need not correspond to that of subject or witness, but should be provided after both the subject and witness have signed.]*