STUDY TITLE: **Understanding Factors that Influence Resistance to Substance Use (aka Substance Use Resistance (SUR) Twin Study)**
PROTOCOL NO.: HM20025077
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Substance Use Resistance (SUR) Twin Study – aka The RESIST Study
Consent for Steps 1 & 2 and Information Sharing

Participation in this research is voluntary. You can choose not to participate at all and even if you start the study, you can change your mind later. There are no loss of benefits to which you otherwise might entitled to if you choose not to participate in this study.

Please think carefully about whether or not you want to complete this research study and only continue if you understand this consent. If you have questions, please contact the MATR and have your questions answered before continuing.

Purpose & Background Information. This research project hopes to **identify factors that help individuals resist developing substance** use problems. When we are taking about substance use, we are talking about drugs (which includes alcohol) and other substances that: 1) have addictive properties and (2) may be purposely used to make people change how they feel. Your responses will be used by our research team to determine all the factors that have influenced any decision to **NOT** use drugs (aka: resistance factors).

Our overall project goal is to develop a measurement tool to be used by researchers for identifying a person's access to and use of important resistance factors against drug use. To help with this goal, the study occurs over two phases. You are being asked to participate in Phase One. During Phase One, you will be asked to provide information and feedback that will be used to help develop a separate research survey aimed at identifying those 'substance use resistance' factors. The research survey developed from the Phase One feedback will be used in Phase Two. You are unlikely to be asked to participate in the Phase Two research survey.

Your Involvement. Your participation is very important because each twin that takes part increases the likelihood that the Phase One participants will truly represent a diverse group of individuals (including those **with and without experiences using substances** like alcohol and/or other drugs). To be in the study the MATR will need your permission to share your name and contact information with the study staff so that they may contact you. This study is separated into three main steps, each with compensation. You may be asked to only complete some of the study steps, which could include:

1. **Step 1: Survey & Brainstorming**
    - **Online Survey** – a survey (approx. 15 min) asking questions about your experiences with substances such as alcohol or other drugs as well as demographic questions.
    - **User Account Creation -** (approx. 2-5 min) using assigned account information (not your own email) on a platform called groupwisdom™.
    - **Brainstorming** – (approx. 15 – 20 min) – brainstorm ideas around "resistance factors" that helped prevent or reduce your use of different substances like alcohol or other drugs. You remain anonymous to other participants while on the platform. Depending on when you begin your brainstorming session, you may see the collected brainstormed ideas provided by each individual participant as they are added and others may see the ideas you add.
    - **Compensation** –a $15 e-gift card.
    - **After you create your user account/brainstorming, your contact information will be shared with the study staff and they may begin contacting you about the other parts of the study.**
2. **Step 2: Create Group Concept Maps** (approx. 20 to 30 min)

- Occurs two to six weeks following Step 1.
- The study staff will ask you to return to your groupwisdom™ account and *sort and rate* the ideas collected from the brainstorming sessions.
- **Compensation** – a $20 e-gift card.

3. **Step 3: Virtual Focus Group Discussion (optional)**
   - Occurs two to six weeks following Step 2.
   - If selected, you will be asked to complete a separate consent so you can say yes or no at that time to the focus group.
   - Completing steps 1 & 2 does not mean you have to do a focus group. If you are selected for a focus group discussion, the study staff will contact you with more details about the focus group. There is a separate consent and compensation ($45 e-gift card) for individuals that complete Step 3.

The study staff has to process information between each step, which can take several weeks. So, while you will only need to do tasks on three separate days, the study requests for these three events might be spread out over approximately two to four months.

Other possible requests: Some participants may also be asked to complete an optional feedback survey related to your experiences during Phase One and your perceived usefulness of the questions and participant responses. The study might also invite a very limited number of participants to test the survey being developed for Phase Two.

What's likely to happen with the information you provide in the Phase 1 Survey. *The data collected with this survey will be kept indefinitely for research purposes by the MATR, or, in the unlikely event the MATR ceased to exist as part of anonymized or de-identified datasets for continued analysis. You are unlikely to be contacted for additional consent for the use of your survey data. In general, we will not give you any individual results from this study.* ***The information you provide (including full and partial responses):***

- ✓ will be shared with the researchers in a de-identified manner, which means the data you provide in the survey will not have your name or other identifying information about you. The only exception to this may be demographic survey items (like race, ethnicity, gender) which could be shared with your identifying information to help the study make sure a wide variety of participants provide feedback.
- ✓ may be saved in a secure MATR database with a random, coded identifier.
- ✓ may be used to determine how many members within our registry have a certain health condition or trait, or to answer basic research questions.
- ✓ may be matched with information about you that is in the Registry database, such as your date of birth, sex, zygosity, ethnicity/race, health, and contact information.
- ✓ may be matched with data collected in previous or future studies following IRB guidelines (The IRB or Institutional Review Board is the organization that governs human subjects research and ensures that research is being done ethically).
- ✓ may be used to determine whether you are eligible for an invitation to participate in other MATR studies. You can always decline these requests.
- ✓ may be matched to DNA and/or other samples you provide for this study, may someday provide, or have already provided to the MATR Repository for future research following IRB guidelines.
- ✓ may be matched with other data collected about you and shared in a de-identified or anonymous format with researchers so that they can answer scientific questions.
- ✓ may be included in scientific presentations or publications; however, your identity will not be disclosed.
- ✓ may be provided as aggregate (totals/bulk) results (e.g. total number or percent of).

Information the Study may share back to the MATR includes your participation status in the study tasks, like if you complete the task or not and the status date as well as updates they might encounter to your contact information or zygosity.

General Risks and Discomforts. Some questions, like those about your substance use experiences, might cause you to feel uncomfortable. You do not have to answer questions you are not comfortable answering and you can stop participation at any time.

Risks Related to Confidentiality of Records & Privacy. Although every reasonable effort has been taken to protect the information you provide, whenever sharing information about yourself there is always a risk of a loss of confidentiality and privacy. If information about your substance use experiences were made known to those outside the study, there could be negative consequences to you. However, we take many steps and have additional protections to help keep this from happening. We have listed those steps below as well as things you can do to help protect your information.

***What <u>WE</u> do to help protect your confidentiality*:**

- Data is collected, de-identified, and stored using approved, secure data-collection methods and software. Data is stored on a secure VCU server that is encrypted, firewalled, and username and password protected.
- Access to the secure databases, data-collection applications, and servers is limited to qualified, approved personnel and requires user accounts and passwords.
- MATR and research staff undergo extensive training in policies to protect the confidentiality of our participants

***What <u>YOU</u> need to do to help protect your confidentiality*:**

- Make sure you are in a location you are comfortable with when completing study elements.
- If completing items online, make sure others cannot access the device you are using while you are completing items and that you exit browsers when finished.
- Be aware that since this study includes twins, although we will not share this information with your twin, they may figure out the following: you are likely a member of the MATR and possibly participating in this study.

In order to monitor the protection of study participants, research records which identify you and your e-consent may be looked at and/or copied by The Department of Health and Human Services (DHHS) agencies; Virginia Commonwealth University (VCU); and the VCU Institutional Review Board (IRB).

Additional Protections. This study has been provided with the National Institutes of Health (NIH) **Certificate of Confidentiality**. Basically, this helps keep your information private, which means other than a few exceptions (like reports of child abuse or harm) we cannot share information from this research with anyone not connected to the research. This is important since we are asking questions about substance use. Having this Certificate means we cannot be required to share anything for civil proceedings or a court case. You should understand that this Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

☐ Please check the box if you would like to see more about what the Certificate of Confidentiality does and does not protect.

[If checked to following descriptive language is provided: A Certificate of Confidentiality helps the researchers keep your information private. For example, we may not give out your information in a civil proceeding or court case. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate cannot be used to refuse a request for information

from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the organization funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Withdrawal of consent. You retain your right to revoke your consent in the future. To do so, you will need to contact the MATR directly (see "MATR Contact Information Section" below) and express this change of willingness. Your withdrawal request will only pertain to future use of your data and cannot be applied to data that has already been shared or is part of scientific publications/presentations.

Costs. Other than your time, there are no costs to participate in this survey.

Benefits. Though you may not benefit directly from taking part, your participation could result in improving the generalized understanding of factors that provide resistance to substance use problems.

Compensation. For completing Steps 1 & 2, you could receive up to $35 in e-gift cards (Mastercard, Amazon, Lowes, Walmart – your choice!). Completing Step 1 qualifies you for $15 and Step 2 completion qualifies you for an additional $20. VCU requirements (see below) must also be completed to qualify for compensation. Participants can choose to not receive compensation.

VCU Requirements for Compensation: VCU's financial offices require that compensation paid to research participants be tracked. This is needed on the off chance you were to receive six hundred or more dollars from VCU in a fiscal year for activities such as research, then that money would be considered taxable. The MATR is required to collect your full name and permanent mailing address to track the study payments. You might also be asked to provide your social security number, but that is optional. It is possible that VCU fiscal offices would request this information as documentation that a payment was made. If this request is made, *no other details about you or your study data would be part of this information.*

MATR Contact Information. If you have questions about the study specifically, you may contact the MATR or the MATR Scientific Director, Dr. Elizabeth Prom-Wormley, by emailing matr@vcu.edu or by calling our toll-free voicemail line at **1-800-URA-TWIN** and **referencing the SUR Study**.

Other Questions. If you have general questions about your rights as a research participant in this or any other research, you may contact the IRB at the VCU Office of Research and Innovation and reference the SUR Twin Study

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Consent to participate.

If you select the "**Yes, I consent/agree to participate**…" option then you are indicating the following: You have read and you understand this consent and any questions you may have had were answered to your satisfaction. *You freely consent to participate in this study and give your permission to have your data used as described in this consent and to having your contact information shared with the study staff.*

Options provided are:

YES, I consent/agree to participate in the SUR Twin Study. The MATR may share my information with the study.
NO, I decline to participate in the SUR Twin Study.