INFORMED CONSENT FORM
AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Yale University / "A Translational and Neurocomputational Evaluation of a D1R Partial Agonist for Schizophrenia"**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

KEY INFORMATION

You are invited to take part in a research study. This research study is studying CVL-562 as a possible treatment for early-course schizophrenia, schizoaffective disorder or related psychotic disorder. The National Institute of Mental Health (NIMH) is funding this research study. The purpose of this research is to test whether an experimental drug can help with thinking and memory in people with schizophrenia.

If you decide to take part in this research study, the general procedures include some clinical assessments and interviews, some computer tests, bloodwork, and a physical exam. Upon successfully completing the screening process, you would complete 7 total study visits (the first may be spread across a few days), 5 of which would be test days involving study treatment with the pill named CVL-562 in which you will receive a randomized dose. Each of the 5 test days will be separated by at least 48 hours. Both you and the research team will not know which dose you are receiving on each day. On each of the 5 test days you will complete a magnetic resonance imaging (MRI) scan after taking the study drug. The most important risks or discomforts that you may expect from taking part in this research include side effects from the study drug (such as nausea and headache), inconveniences associated with behavioral testing (sensitive information may be asked for), risks from intravenous (IV, directly into the vein) catheter placement (bruising, bleeding) or venipuncture (blood draw), risks from optional genetic testing (all data and results will be made anonymous and kept in a secure location) and risks from a MRI (headache, anxiety, dizziness). Possible benefits to others include helping understand the underlying science and treatments for people with schizophrenia.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you have met the study criteria following a phone interview and because you are likely to meet criteria as a subject with schizophrenia, schizoaffective disorder or related psychotic disorder (or are suspected you may meet these criteria) in the past 10 years.

The purpose of this research study is to:

- Test the effectiveness of the study drug, CVL-562, on regions of the brain that are responsible for thinking and memory in subjects with schizophrenia, schizoaffective disorder or related psychotic illnesses.
- Test the effectiveness of the study drug, CVL-562, on thinking and memory in subjects with schizophrenia, schizoaffective disorder or related psychotic illnesses.
- Test how individual responses to the study drug, CVL-562, may serve as predictors of thinking and memory, which will be examined using a number of questionnaires.

This is a research study to test a new investigational drug. An investigational drug is one that is not approved by the United States Food and Drug Administration (FDA). As part of this study you will randomly (by chance, like flipping a coin) receive a different dose of the study drug on different test visits. One of these days will have a placebo dose, meaning that it will be an inactive substance.

About 120 subjects will participate in this study.

WHAT WILL HAPPEN DURING THE STUDY

Your participation in this study will last approximately 2 months over 7 total visits. Each visit will last up to 8 hours. The first visit may be split across a few days, due to length of tests and your availability.

<u>Screening</u>:

Before any study-related tests and procedures are performed, you will be asked to read, sign and date this consent document. The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- Structured clinical interviews and assessments
- Behavioral scales, suicidality assessment and computer tests
- Urine toxicology
- Urine pregnancy test (for females only)
- Baseline bloodwork (complete blood count with differential, comprehensive metabolic panel, Hepatitis B, Hepatitis C, HIV - the study doctor may be required by law to report the result of these tests to the local health authority, optional genetics blood samples)
- Electrocardiogram (EKG), vital signs, physical exam
- MRI safety questionnaire and an optional mock scanner experience
- Testing for Covid-19

This first visit may be split across a few days, due to length of tests and your availability. If you qualify to take part in this study and go on to receive the study treatment, then the following will happen:

Study Treatment:
You will receive one of 5 possible doses on each day. 4 of these doses will be of the study drug, and one will be a placebo, otherwise known as an inactive substance. This is a double-blind study, which means neither you nor the study doctor and staff will know to which of these study drug groups you are assigned. In case of an emergency, however, the study doctor can get this information.

You will have the following study visits and undergo the following procedures:

- Visit 2 (6-8 hours)
    - Clinical assessments and questionnaires
    - If you have not eaten a meal within 2 hours prior to the start of this visit, you will be given a small meal to eat before receiving the study drug. This is because the timing of the study drug's effects is different when you have a full versus empty stomach.
    - Urine sample for toxicology
    - Urine pregnancy test (for females only)
    - Vital signs
    - Study drug will be administered
    - Vital signs will be re-checked after study drug administration but prior to entering the MRI scanner, as well as after you finish the MRI scan.
    - An intravenous (IV) catheter will be placed in your arm to draw blood so we can measure the amount of study drug in your blood before you begin the MRI scan, and after you finish the scan. The IV will be removed after the last blood draw.
    - The MRI scan will take approximately 90 minutes (up to 2 hours).
    - Clinical assessments and computer testing will be administered post MRI scan.
    - You will be observed for at least 2 hours following dose administration.
    - A study doctor will be available for the entire test visit.
- Visits 3, 4, 5, 6 are identical to Visit 2, with at least 48 hours between the start of each test visit day. You will be phoned approximately 24 hours after each visit (Visits 2-6) to briefly assess for any side effects. You will be given a phone number to call if you have questions in between visits.
- Visit 7 – Follow-up visit (approximately 2 hours): Individual follow-up and de-briefing. Final bloodwork will be obtained at this point (complete blood count with differential and complete metabolic profile). At this visit, all female subjects will receive a final urine pregnancy test. You may call the phone number on the first page of the consent form if there continue to be questions after you are discharged from the study.

After Study Treatment:
Because this is a research study, the study drug will be given to you only during this study and not after the study is over. You will be called approximately 1 month after this follow-up visit to assess for possible long-term effects, if any.

Covid-19 Precautions:
Because of the recent Covid-19 pandemic, we will test you for Covid-19 at the start of the study, and we ask that you contact us if you have a change in symptoms or have a positive test for Covid-19 during the study. If you are found to test positive for Covid-19 at the start of the study, we will ask that you self-isolate and test according to current CDC guidelines. If, at the end of 10 days, you have no symptoms you may be assessed to re-join the study. In addition, during the study procedures, study staff may make accommodations to ensure social distancing and proper hygiene. This will include doing some parts of the study while you and the study staff are in separate rooms using a secure videoconferencing system. Finally, as the risk of getting Covid-19 increases with social interaction, we would like you to follow current guidelines for Covid-19, including wearing a mask when you leave the home to come to participate in the study. Once you are at the study site we ask that you continue to wear a mask when you will be in contact with study staff. We will provide a mask for you if you do not have one.

EXPECTATIONS
If you participate in this study, you will be expected to:

- Sign and date this informed consent.
- Attend each visit.
- Take the study drug as expected.
- Not drive yourself to and from test days. We can arrange for transportation to bring you back and forth.
- You may not be pregnant or intend to become pregnant during the trial. If you are female, you must be willing to use a form of birth control during the study and for up to 1 month after you complete the study.
- For your first visit with us, you must be willing to abstain from recreational substance use until your urine test shows no drugs; this would involve more regular urine testing.
- You must be willing to abstain from recreational substance use until the study is finished. If you are found to have used substances during our study, we may need to exclude you from the study, as we will be checking your urine at each study visit except for the final visit.
- You (and your prescribing provider) must be willing to continue on your current medication dose during the course of this study.
- You must be willing to abstain from having grapefruit juice or other substances that can affect metabolism of other drugs (please check with the study staff about which drugs are included).
- You must be willing to abstain from daily use of drugs that work a certain way (including drugs to help you sleep like Ambien, or Lunesta; or drugs to help you feel calmer like

Valium, Klonopin) for more than 10 days prior to starting the study, and during the study.
- You should contact the study staff if you experience severe nausea, vomiting, extreme headaches, or other symptoms that you think could be related to the study drug.
- You should contact the study staff if you experience symptoms that could be related to Covid-19, including, but not limited to, fever, fatigue, cough, difficulty breathing, diarrhea or a sudden loss of smell.
- You should contact the study staff if you test positive for Covid-19 at any point during the study.
- Wear a face mask when transporting to the study site, and comply with hygiene requirements during the study visits.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

For CVL-562:

Frequent

- Nausea
- Vomiting
- Headache
- Feeling tired

Rare

- Abdominal pain
- Dizziness or light-headedness

We will have medications on hand during the MRI scan to help with some of these side effects if they occur.

RISKS OF STUDY PROCEDURES

Blood samples

Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.

Intravenous (IV) catheter

Possible side effects can include bruising, infection and clotting at the site of IV insertion.

Venipuncture (blood draw)

Possible side effects can include bruising, bleeding, and infection at the site of blood draw.

Electrocardiogram (EKG)

Skin irritation is rare but could occur during an EKG from the electrodes or gel that is used.

Questionnaires

The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.

Magnetic Resonance Imaging (MRI)

Magnetic resonance imaging (MRI) uses magnetic fields and radio waves to take pictures of the body. Millions of people have had MRI scans with no known safety issues. MRI uses a strong magnet, which can pull strongly on some metals. These metals must not be brought into the scan room. They could be pulled towards the magnet and cause serious injuries if they hit you. People entering the scan room must remove all metal from their body, clothing and pockets. This includes jewelry, hearing aids, watches, cell phones, keys, coins and wallets. Some metal objects could also heat up during the MRI, burning you.

There is also a potential risk of MRI for subjects with medical implants or other metallic objects in their body. All subjects undergoing MRI scanning must complete a risk evaluation screening in advance of the study for the presence of medical implants or other foreign bodies that could pose an injury. Every effort will be made to ensure that disclosed implants or foreign bodies do not pose a risk to subjects. In cases where there is insufficient information to evaluate the risks associated with an implant or foreign body, the MRI study will not be allowed to proceed. Electrical devices such as pacemakers could go wrong or stop working. You must also tell us if you are wearing anything that could contain metal. For example, some medication patches have a metal backing. Some clothing can contain metal fibers that could also heat up during the MRI. We will therefore ask you to fill out an MRI safety form to check if you have anything in your body which might be dangerous in the MRI. It is very important that you fill out this form accurately and ask if you are unsure about anything.

During the MRI scan, you may feel uncomfortable or worried. When the MRI scanner is making pictures, it makes loud tapping, buzzing, and beeping noises. Without protection, this could damage your hearing. We will give you earplugs to reduce the sound to a safe level. While the MRI scanner is making noises, we will not be able to hear you. We will give you a squeeze bulb for you to contact us.

You will get an MRI scan for research purposes only. The MRI scans performed in this study are not designed to find abnormalities or for your healthcare. The study doctors, the lab, the technician performing the scan, and the site where the MRI scan takes place are not qualified to interpret the MRI scans for healthcare or diagnostic purposes. If we see a worrisome finding on your MRI scan, a radiologist or another doctor will look at the scan and will communicate these concerns to your regular doctor. You can decide with your regular doctor whether you should have another scan for healthcare or diagnostic purposes. If you have another MRI scan, you or your insurance company may have to pay. We are not responsible for whatever decisions you and your regular doctor make.

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel:

Fax:

Although there are no known risks related to MRI on pregnant women or a fetus, there is a possibility of yet undiscovered pregnancy related risks. Since there is no possible benefit from participating in this protocol for a pregnant woman, we will exclude pregnant women.

Placebo Risks

If you receive placebo (the inactive substance) as part of this study, your symptoms of schizophrenia, schizoaffective disorder and other related psychotic disorders may not improve or may get worse.

UNFORESEEN RISKS

Since the study drug, CVL-562, is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus (unborn baby) if you or your female partner become pregnant.

BIRTH CONTROL RESTRICTIONS

Taking the study drug may involve risks to a pregnant woman, an embryo, fetus (unborn baby), or nursing infant. Therefore, if you are pregnant, planning to become pregnant, or are breastfeeding a child, you cannot participate in this study.

Females:

In order to reduce the risk of pregnancy, you should use an effective method of birth control while you are participating in this study and for 1 month after your last dose of the study drug. Acceptable methods of birth control for use in this study are Intra-Uterine Devices (IUD), hormonal contraception, abstinence, or condoms. The study doctor or study staff will discuss this with you.

If you become pregnant while you are participating in this study or within 1 month of your last dose of study drug, tell your study doctor or study staff immediately. The study drug will be stopped if you are still enrolled, and your participation in this study will be ended.

ALTERNATIVES TO PARTICIPATION

You do not have to be in this study to receive treatment for your diagnosis. This research study is for research purposes only. The only alternative is to not participate in this study. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

NEW FINDINGS

You will be told of any significant new findings that are developed during the course of your participation in this study that may affect your willingness to continue to participate.

BENEFITS
This study is not intended to improve your condition, even if the study drug favorably influences your mental illness, the positive impact will not last beyond the brief study period. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION
«Compensation»

You will be paid up to a total of $2,910.00 if you complete this study. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments. You will be paid for the visits you complete according to the following schedule:

Visit 1: (4-8 hours):
Clinical Assessments: $80
Computer Tests: $40
Medical Assessments: $40
Total = $160

Visit 2: Test visit (6-8 hours):
Pre-Scan Clinical Assessments: $40
Medical Assessments: $40
MRI Scan: $250
Post-Scan Computer Tests: $50
Post-Scan Clinical Assessments: $40
Total = $420

Visits 3, 4, 5, 6: $1,680 total, $420 per visit (these visits will be identical to Visit 2 and you will be paid for the procedures you complete in these visits, as described for Visit 2)

Additional MRI scan (collected at 1 of the visits): $150

Visit 7: Follow up debriefing interview (2 hours):
Follow-up interview: $80
Medical Assessments: $20
Total = $100
Bonus: $400 once you have completed all visits

If you do not complete the study, for any reason, you will be paid only for the parts of the study that you do complete. You will be paid after each visit. If you have any questions regarding your compensation for participation, please contact the study staff.

Reasonable transportation costs will be reimbursed. Please contact the study staff prior to your study date to discuss your transportation plans and confirm they are appropriate for reimbursement.

CONFIDENTIALITY

Records of your participation in this study will be held confidential except when sharing the information that is required by law or as described in this informed consent. We have a Certificate of Confidentiality from the National Institutes of Health (NIH). The study staff, Yale University, or persons working on behalf of Yale University, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) of record will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

If you decide to be in this study, the study staff, which may include the study doctor, will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, your address, and your contact information. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The study doctor will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the study doctor or selected members of the research team. Any information that can identify you will remain confidential. Additionally, any research-related material will be stored in locked cabinets and password protected if stored on a computer. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept until the study doctor decides to destroy the link, and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. 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 (see below); 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 agency which is 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. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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

COMPENSATION FOR INJURY

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured, then they will help you get the care you need**.**

Yale University does not provide funds for the treatment of research-related injury. Your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury is available.

By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

COSTS

There will be no charge to you for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

FUTURE RESEARCH STUDIES

Identifiers will be removed from your identifiable private information or identifiable biospecimens collected during this study and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

CLINICALLY RELEVANT RESULTS
Research results that are clinically relevant, including individual research results, will be disclosed to you if something medically relevant arises requiring additional follow-up.

OPTIONAL GENOME SEQUENCING
Researchers can look closely at large amounts of your genetic information by sequencing, or "reading", the letters in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. The research might include whole genome sequencing (that is, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). Exomes contain the part of the DNA that tells our bodies what proteins are to be made.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00041355.

CONSENT FOR OPTIONAL SPECIMENS FOR FUTURE STORAGE/GENETIC TESTING:
You are also being asked to participate in an optional sub-study. We may request to draw a blood sample to obtain DNA. If we do, we will ask for about two ounces of blood (equivalent to four tablespoons), which is less than one-sixth the amount of blood that the Red Cross routinely collects in blood drives. The major purpose of this work is to test enough genetic markers throughout your genome (the full set of your DNA) to identify one or more markers close to genes influencing risk for neuropsychiatric illness. We also hope to identify genes that influence some of the other behaviors and characteristics we will ask you about and genes that influence other things about you that might be measured as part of your involvement in research, depending on what other studies you might participate in or have participated in already. (A

marker is used to locate a specific place in the genome that varies between individuals.) Once such markers are identified, we hope to be able to locate and describe the genes that may be related to schizophrenia. This could lead to new treatments or new means of prevention for some of these problems.

Indeed, we know that different individuals' genes make a substantial difference in whether or not they develop the symptoms of psychiatric disorders. However, we do not yet know which genes influence different peoples' risk of developing symptoms. By collecting specimens of serum molecules and DNA from subjects with schizophrenia or related disorders, and comparing it with specimens of serum molecules and DNA from subjects with other psychiatric disorders or with no psychiatric diagnosis, we aim to identify some of the key molecules and genes that influence the disorder. This would help us better understand the biology of schizophrenia and other severe psychiatric disorders, which may lead to improved treatment in the future. In addition, we hope to find genetic differences that will help us predict who will respond to which treatments (either medications or psychotherapy); this would allow us, in the future, to choose the best treatment for an individual patient on the basis of a blood test.
In order to do that, we created a research database or bank where data and blood samples collected from you can be used for future research projects. The specimens and data collected in this bank will be used by researchers who obtained the approval by their Institutional Review Board to study schizophrenia and bipolar or related disorders.

You are invited to allow some of your samples (called specimens) and related information to be stored (banked) for future research to examine risk associated with developing psychiatric illness. This may help researchers in the future learn more about how to prevent, find, and treat neuropsychiatric illness. If you agree to participate, the information about you that will be held in this Research Clinic database will include an identification code used on your blood sample to keep it anonymous to those utilizing it. Your identifiable information will only be accessed by the study doctor and authorized members of the research team and will be kept in a separate secure database and contain your age, medical record number(s), demographic information, medical and psychiatric history, symptoms, risk factors, symptom checklists, outcome of diagnostic instruments, laboratory and clinical test results, and results of research tests such as neuroimaging results. If you have previously or are still participating in other research studies in our clinic, we will ask you to allow us to include the data collected in the course of these other studies in this repository as well.

We will also use your DNA to study differences in genes between individuals. Most of the markers we will study have no meaning, that is, they do not have any particular function – we will use these markers to identify specific locations in your genome. We may also study specific genes that may relate to aspects of brain function (for example) or other physiological function. Participation in the serum/genetic specimens' portion of this study will require nothing from you other than a blood draw. As noted, in most cases we are able to simply collect three small tubes of blood during the blood draw for your screening tests during evaluation. The serum/genetic samples and related data sent to the lab are identified only by a code identifying our clinic and a sample number. Your specimens will be kept indefinitely but the link to the

code is accessible only by the study staff and the study doctor and so all serum/genetic information is strictly confidential.

Your specimens will be stored for an unlimited time. The blood will be kept at the central site of this study Yale University in New Haven, Connecticut. If the genetic data is extracted from your blood, it will be stored at a repository at the National Institute of Health (NIH) in Bethesda, Maryland. This institute sponsored this study. When your specimens are stored, we are careful to try to protect your identity from discovery by others. As noted, your samples will receive a unique code. Other researchers will only receive coded samples and de-identified information, and will not be able to link the code to you. Strict security safeguards are in place to reduce the chance of misuse or unplanned release of information. Using your specimens for research will probably not help you. We do hope the research results will help people in the future. Research results will not be returned to you or your regular doctor. If research results are published, your name and other personal information will not be given.

There is a risk that your information could be misused. The chance of this happening is very small. We have protections in place to lower this risk. There can also be a risk in uncovering genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Very rarely, health or genetic information could be misused by employers, health insurance companies, and others. There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers (except those with fewer than 15 employees) to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Your specimens and information will only be used for research and will not be sold. There is a possibility that this research may lead to development of products that will be commercialized. If this happens, there is no plan to share any financial gain with you.

The choice to take part is up to you. You may choose not to let us store and use your samples, and your care will not be affected by this decision. If you decide that your samples can be kept, you may change your mind at any time. Please contact the study staff to let them know you do not want your samples used any longer. Your samples will either be destroyed, or made permanently anonymous (the code linking them to you will be destroyed). You must follow up this request by contacting the study doctor.

Under some circumstances, you may have previously or concurrently participated in other protocols in our clinic and we seek to confidentially include the clinical, research, and outcome data collected in those studies in this repository. This consent form is meant to apprise you of this data-sharing and give you the opportunity to allow or to refuse it. If you decline consent to share data between the other protocols in which you have participated and this genetic trial, then such data from any other trials will not be included in this repository.

You may decide not to participate in the optional sub-study. If you decide not to participate in the sub-study, your decision will have no impact on your ability to participate in the main study and will have no impact on any other benefits to which you would otherwise be entitled.

Please indicate your preference below:

❒**YES** _____ (initials) I agree to have blood drawn for future serum and genetic investigations.

❒**NO** _____ (initials) I do not agree to have blood drawn for future serum and genetic investigations.

OPTIONAL RECORDING OF STUDY PROCEDURES

Because we may be doing some study procedures through videoconferencing, we may need to review the procedures to ensure that our data collection is accurate. To do this, we would record your study procedures in order to review them with other trained study staff. All videos will be recorded and stored in a secure format and location, and password protected. These videos will only be accessible to specific study staff for the purposes of validating that the data collection is accurate. It is optional to agree to this for participating in the study.

❒**YES** _____ (initials) I agree to allow my study procedures to be recorded, stored and reviewed.

❒**NO** _____ (initials) I do not agree allow my study procedures to be recorded, stored and reviewed.

POSSIBLE PARTICIPATION IN FUTURE STUDIES

We would like to be able to contact you in the future to offer you participation in other studies. Giving your permission for the research team to contact you does not obligate you to answer any future questions or to participate in any future research – you always have the right to decline further participation in research. If you agree to participate in another study, we would ask you to read, sign and date a new consent form. Please initial if you would like to be contacted to participate in other studies.

❒**YES** _____ (initials) I agree to be contacted for future research studies

❒**NO** _____ (initials) I do not agree to be contacted for future research studies.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and research team will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all laboratory test results.
- HIV / AIDS, Hepatitis infection testing results.
- Sexually transmitted diseases or other reportable infectious diseases.
- Physical exams.
- The diagnosis and treatment of a mental health condition.
- Use of illegal drugs or illegal behavior.
- Records about any study drug you received.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the research team may share health data about you with authorized users. Authorized users may include

- Representatives of NIMH.
- Representatives of Yale University, Columbia University/Research Foundation for Mental Hygiene (RFMH), State University of New York (SUNY) Stony Brook, University of Pennsylvania and Cerevel Therapeutics.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this research.

- A data safety monitoring board which oversees this research.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if CVL-562 works and is safe.
- For other research activities related to CVL-562.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered will still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing or biasing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

_____

Printed Name of the Person Obtaining the Authorization

_____ _____

Signature of the Person Obtaining the Authorization Date