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

| | |
|---|---|
| **Sponsor / Study Title:** | **Clindove Research LLC / "Pre-screening survey for Metabolic, Cardiovascular, Obesity, Mental Health and Endocrine Trial Eligibility (DOVE- MET- COME- 100)"** |
| **Protocol Number:** | **METCOME062025** |
| **Principal Investigator: (Study Doctor)** | **Nelly Cohen, MD** |
| **Telephone:** | **516-518-3239 (24 Hours)** |
| **Address:** | **Clindove Research LLC<br>1349 Broadway<br>Brooklyn, NY 11221** |

## 1. Introduction

You are being asked to take part in a metabolic, cardiovascular and psychiatric pre-screening study focused on diabetes, cardiovascular diseases, related metabolic conditions, and mental health issues (such as mood, stress, mental health condition, and cognitive functions), and/or potential relationship between metabolic and mental health. This pre-screening will help determine your eligibility for future clinical research studies.

As part of this process, we will collect information on your demographic background (including age, sex, race/ethnicity), family history of metabolic disorders/any psychiatric illness, medical history, and current medications. Additionally, you will meet with research coordinators who will assess your medical history and current health status. These assessments will help identify clinical studies that may be suitable for your participation.

Participating in the study is voluntary. If you decide to complete it, you can also change your mind at any time. Before you decide, it is important that you understand why the study is being conducted and what your participation will involve. Please read this document carefully and ask any questions you may have.

## 2. Purpose of the study

Clindove research is committed to implementing a structured pre-screening study plan designed to:

- Identify individuals with **metabolic and cardiovascular dysfunctions**, including diabetes, metabolic syndrome, obesity, cardiovascular disease (e.g., hypertension, heart failure, atherosclerosis) and chronic kidney disease (CKD)
- Identify individuals with **common psychiatric conditions**, including depression, anxiety and psychotic disorders
- Assess psychiatric symptoms severity, assess the patient's compliance with antidepressant medications, their progress, the medication's effectiveness and non compliance of antidepressant medications.

Approximately 7000 participants will take part in this study.

This initiative aims to support potential participation in future clinical research studies by ensuring that individuals who may benefit from targeted interventions are identified efficiently and ethically.

## 3. Screening Procedures

If you decide to join this pre-screening study, the research team **may do some or all of the following**, depending on **what is needed for you**:

• **Review your medical history** – This includes asking about your age, sex, race/ethnicity, family history of conditions like heart disease, diabetes, or mental illness, as well as any medications you are currently taking.
• **Check your physical health** – The team may measure your height, weight, body mass index (BMI), waist size, blood pressure, and heart rate.
• **Do lab tests** – You might be asked to give a blood (approx.. 15-25mL) or urine sample to check things like:

- Blood sugar/ **Hemoglobin A1c (HbA1c)** to assess diabetes risk
- Kidney and liver function by checking **Comprehensive Metabolic Panel** (including Basic Metabolic Panel with albumin, total protein, bilirubin, and liver enzymes), **Creatinine and eGFR (Estimated Glomerular Filtration Rate)** (for kidney function assessment)
- Cholesterol and heart health by checking **lipid profile/cholesterol, Lp(a) (Lipoprotein a – a genetic risk factor for cardiovascular disease), NT-proBNP (marker for heart failure)**
- Hematology and coagulation profile by checking **PT/INR (Prothrombin Time Test and International Normalized Ratio Test), PTT/aPTT (Partial Thromboplastin Time), CBC (Complete Blood Count)**
- Inflammation levels by checking **hsCRP (High-sensitive C-Reactive Protein)**
- **Uric acid panel**
- Protein levels in your urine to check kidney health by checking **Urine**

**Protein-to-Creatinine Ratio (UPCR)** (for assessment of protein in the urine and nephropathy)
- Urine sample to detect drugs or pregnancy

*You may not be asked to complete every test. Only those necessary based on your responses will be conducted.*

• **Mental health screening** – You may be asked to complete short questionnaires about depression, anxiety, and general mental health by using:
- **Patient Health Questionnaire-9** (PHQ-9) for depression
- **Generalized Anxiety Disorder-7** (GAD-7) for anxiety
- **Brief Psychiatric Rating Scale** (BPRS) for general psychiatric symptoms
- **Mini-International Neuropsychiatric Interview** (MINI) for diagnostic screening.

**4. Duration of the visit**

The duration of the visit will range from **30 minutes to 100 minutes**, depending on the number of tests required:
- Screening procedure including blood work will take approximately **30 minutes**
- Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder-7 (GAD-7) will take approximately **10 minutes**
- Brief Psychiatric Rating Scale (BPRS) will take approximately **15-30 minutes**
- Mini-International Neuropsychiatric Interview (MINI) will take approximately **15-30 minutes**

**5. Potential Risks and Benefits of the Screening**

There may be some risks in the study, but these foreseeable risks are generally minimal and temporary. There may be risks that are unknown.

**Metabolic Risks:**

You may feel some discomfort or anxiety during the blood draw. It may hurt for a short time, sometimes the area where the needle was inserted might feel sore or become bruised. Some potential incidental findings may require follow-up.

**Psychiatric Risks:**

• You may have emotional distress due to sensitive topics.
• You may feel uncomfortable while discussing psychiatric symptoms.
• Privacy concerns (mitigated through confidentiality measures).

**Benefits of participation:**

• As part of the study, you will get a baseline of your physical and mental health through blood tests and questionnaires at no cost.
• You will have an opportunity to participate in future clinical trials targeting metabolic diseases and mental health conditions.
• There is, however, no guarantee that you will benefit from your participation in this study.

Information learned from the study may help other people in the future.

**6. Eligibility Inclusion Criteria:**

• Any participant of age 18 years and over who are willing to provide informed consent and participate in the pre-screening study and comply with study procedures.

**Exclusion Criteria:**

You cannot participate in the study if :

• You are pregnant or breastfeeding
• You have severe cognitive impairment or inability to provide informed consent
• You have acute psychiatric emergencies requiring immediate intervention/hospitalization
• You are currently participating in another research study that conflicts with pre-screening data collection
• You are having known history of drug/alcohol misuse

You are having medical conditions that, in the study doctor's opinion, could compromise the integrity of the screening process or pose significant risks to the participant's health.

**7. Next Steps after pre-screening visit**

After completing the screening, you will be informed about the next steps. If you qualify for a future clinical study conducted by Clindove research, we will contact you with details on how and when to proceed.

If you are not eligible for the current study, we will keep your screening information on file. If you meet the criteria for a future study, we will contact you with further details.

**8. Costs of completing the visit**

You will not be charged for any test(s) or any procedure(s) for the visit.

**9. Compensation**

If you choose to participate in the study and complete the consent and screening process, you will receive compensation via a prepaid gift card - $20 for the metabolic evaluation and $20 for the psychiatric health evaluation. You will be paid following the completed visit.

## 10. Privacy and confidentiality

We will keep your information secure using encryption, and only our research team can access it. However, absolute confidentiality cannot be guaranteed.

If you consent to participate in the study, we will use and share your records of study participation only with the parties listed below:

- Advarra Institutional Review Board (IRB)
- Regulatory authorities, including inspection by the United State Food and Drug Administration (FDA)
- Third-party databases (to check whether you have participated in a prior study)
- Clindove Research Team and business associates of Clindove Research.

**Requirement and involvement of Third-party databases :**

To prevent duplicate participation, limited personal information (such as initials, gender, date of birth, and partial license digits) may be entered into secure, encoded databases. This data remains in the system even after study completion and is stored in a de-identified format to protect confidentiality. If a close match is found in another study, additional details such as study indication and participation dates may be shared with researchers to verify eligibility. If you are identified as a match, participation may not be permitted. You may contact the study doctor at any time to review your data or withdraw consent for its use.

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.

## 11. Legal Rights

Signing and consenting to this form does not waive or diminish any of your legal rights.

## 12. Funding and Conflict of Interest Disclosure

This screening study was developed and funded by Clindove Research. The organization designed the study plan and is providing financial support to allow the study doctor to conduct the research.

Participation in this screening study may determine whether you are eligible for future research studies. Some of these future studies may be funded by pharmaceutical companies or other sponsors. If you choose to participate in one of those sponsored studies, the research site and its staff, including the study doctor, may receive financial compensation from the sponsor.

Because the same study doctors may be involved in both this general screening and other industry-sponsored studies, they could benefit financially if those studies are successful.

If you have any questions or concerns about this, please speak with the study doctor for more information.

**13. Voluntary Participation and Right to withdraw**

Participation in this study is completely voluntary. You may withdraw at any time at no cost without any penalty or impact on your medical care or other services.

**14. 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 such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

**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 participants. If you have any questions about your rights as a research participant, 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: Pro00088227.

## 15. Additional information about participating in this pre-screening study

It is solely your choice if you wish to participate in this screening study. No one can force you to participate including the study doctor and study team. You have your right to choose not to participate, or leave the screening at any time, without any loss of benefits to which you are otherwise entitled, cost, or penalty. If you have questions not answered in this consent form, you can ask the study team. Your signature below provides your consent for participation in this study.

This research study is for research purposes only. The only alternative is to not participate in this study.

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Your participation in this study may be discontinued by the study doctor or sponsor at any time for the following reasons:

- If continuing the study is no longer in your best interest.
- If you choose not to consent to updated study procedures or changes that may affect you.

Should your participation be discontinued, you will be informed of the reason and provided with any necessary follow-up care or guidance.

**16. Consent**

Please check the appropriate box to indicate your participation:

☐ I agree to participate in the metabolic health evaluation. ☐ I agree to participate in the psychiatric health evaluation. ☐ I do not wish to participate in this study.

By signing below:

- I confirm I have read and understood this consent form.
- All my questions have been answered to my satisfaction.
- I agree to participate in the study voluntarily.
- I understand I may withdraw at any time without penalty.
- I will receive a signed and dated copy of this form.

Printed Name of Participant

Signature of Participant Date

Printed Name of the Person who explained the Consent Form

Signature of the Person who explained the Consent Form Date

*You will be given a copy of this consent form once completed.*

## AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff 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 test results.

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 study staff may share health data about you with authorized users. Authorized users may include

- Representatives of Clindove Research LLC.
- 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.
- Governmental agencies of other countries.
- 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.

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

- To identify and pre-screen adults at risk for metabolic, cardiovascular, endocrine related disorders or psychiatric disorders for trial eligibility in future Clindove Research studies.
- For other research activities related to the pre-screening activities for metabolic, cardiovascular, endocrine related disorders or psychiatric disorders.

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 may 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 the study results. When the study is over, you can access your study health data.

If you decide not to sign 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 this form.

Printed Name of Participant

Signature of Participant Date