CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY AND AUTHORISATION TO DISCLOSE HEALTH INFORMATION

Study Title: The Safety and Tolerability of COMP360 in Participants with Post-traumatic Stress Disorder

Protocol Number: COMP 201

EudraCT Number: 2021-002621-19

Sponsor: COMPASS Pathfinder Limited, [redacted], [redacted]

Study Doctor: to be added by study site

Address: to be added by study site

Telephone: to be added by study site

Participant Number: to be added by study site

For questions or complaints about your rights as a research participant, contact:
<<IRB/IEC contact details to be added by study site/Regulatory>>

You are being invited to take part in this clinical research study. **Your participation is entirely voluntary, meaning that you can say yes or no.**

This document is called an "informed consent form". It describes the purpose and procedures of the research, including the risks and possible benefits, and how your medical information will be used. You can take a copy of this form home to review. If you wish, you may ask advice from others, such as your personal doctor or family, before you decide.

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. You may ask questions before you decide to start the study and at any time during the study. 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 or not to take part.

If you decide to take part, you will be asked to sign your name at the end of this consent form. You must sign this form before any study-related tests and procedures can be performed. Only sign this form when you fully understand the details about the study and agree to the commitment. You will be given a signed copy of this form to keep, to show you agreed to take part.

After signing this informed consent form, **you are free to change your mind**—at any time—and leave the study if you wish; without giving a reason. If you decide not to participate, or if you decide to stop being in the study, this will not affect the standard of care you receive, there will be no penalty, and you will not lose any benefits which you would otherwise have. You will not give up any legal rights by signing this form.

You will be told about any new information found during the study that may affect whether you want to continue to take part. You will receive this information verbally and in writing. You may be asked to sign a new consent form if this occurs.

1 INTRODUCTION

You are being invited to take part in this clinical research study because you have post-traumatic stress disorder (PTSD). This research study will be conducted by COMPASS Pathfinder Limited (referred to as the Sponsor in this informed consent form).

In this research study, an investigational medication called COMP360 is being tested for the treatment of PTSD. Research suggests that psilocybin may help in treating PTSD. COMP360 is a synthetic form of psilocybin, a chemical compound found in some species of mushrooms. COMP360 works on the serotonin system in the brain which is linked to the regulation of mood.

The psilocybin experience varies greatly between individuals. Psilocybin may temporarily change the way objects and people appear to you. For example, the size and shape of things can appear distorted, walls may appear to move as if they are made of fabric or as if they are "breathing", shapes and colours may be seen on surfaces and the room may appear to get bigger or brighter. You can close your eyes during the experience and wear an eye mask, which we will provide. With your eyes closed, you may see shapes and colours and unusual images as if you are dreaming. Time may appear to pass more slowly, and it may be hard to judge how much time has passed.

Some people have reported visions of their pasts; for example, they might feel as if they are remembering or even reliving events from their childhood. It is sometimes difficult to know if these visions are real memories or fantasies, and the study team will not be able to confirm whether these memories are factual or not, but they will be there to support you if this experience occurs.

Many people find the effects of psilocybin quite pleasant, but others can get anxious because the experience is unfamiliar. The study team and your therapist are specially trained to prepare and support you through this experience. Your therapist will be with you at all times and will be able to help you if you do get anxious.

COMP360 is an investigational medication because its safety, effectiveness, and/or how it works is still being studied. COMP360 has not yet been approved for sale by government agencies in any country (including the Medicines and Healthcare Products Regulatory Agency [MHRA] or the US Food and Drug Administration [FDA]), as a treatment for any condition. Investigational medications like COMP360 may be tested in research studies such as this one. This study is being conducted for research purposes only.

The research study in which you are being asked to take part has been reviewed by the responsible Institutional Review Board (IRB)/Independent Ethics Committee (IEC). An IRB/IEC is a group of scientific/medical experts and regular people who review any research conducted in humans to protect the welfare, rights, and privacy of the participants in the study. If you have any questions or complaints about your rights as a research participant, please contact the IRB/IEC using the contact details on the first page.

2 WHAT IS THE PURPOSE OF THE RESEARCH STUDY?

The main purpose of this study is to investigate the safety and tolerability (whether side effects can be handled by a participant) of COMP360. The research study also aims to determine if COMP360 can help lessen the symptoms of PTSD.

3 INFORMATION ABOUT THE STUDY

Approximately 20 participants (males and females) who are currently suffering from PTSD after a traumatic event experience in adulthood, aged 18 years and older, can take part in this research study. This study is being conducted in study clinics in the United Kingdom (UK) and the United States (US).

This is an open-label research study. Open-label means that all participants who are enrolled will receive COMP360, which means that you, the Sponsor, and the study staff who treat you will know you are receiving COMP360.

There will be 1 treatment group in this study. At the study clinic, you will receive a single 25-mg dose of study medication, consisting of 5 capsules containing 5 mg of COMP360.

Your total participation in this study will be a minimum of 15 weeks and up to approximately 18 weeks. This includes the following:

- A screening period (to confirm that you are suitable for the study, meet with a trained therapist, and prepare for receiving the study medication) of a minimum of 3 weeks and up to 6 weeks.
- Dosing day (where you will receive the study medication, COMP360) following completion of your screening period and baseline visit. Baseline visit is a visit when certain tests will be done and that is performed one day before dosing day.
- A safety follow-up period (to check your overall health) during which time you will attend the study clinic for regular visits over approximately 12 weeks.

During the screening period, if you are taking a certain antidepressant and/or antipsychotic medication(s) (those that affect your behaviour, mood, thoughts, or perception), you will be required to start reducing your current dose over the course of 4 weeks before the baseline visit and study treatment. You should be completely off your antidepressant and/or antipsychotic medication(s), 2 weeks before the baseline visit and the first preparation session. If you are taking certain antidepressant and/or antipsychotic medication(s), you will be required to stop using them at once (without reducing the dose first). You will need to be off these medications for 4 weeks before receiving COMP360. You will need to remain off your PTSD medication(s) for at least 4 weeks after receiving COMP360. The study team will discuss this with you and support you through the withdrawal period.

If you are discontinuing antidepressant and/or antipsychotic medication(s) during the screening period, you will be evaluated at the clinic weekly for a minimum of 3 weeks and up to 6 weeks before you receive COMP360 to ensure your safety. In between your in-person screening visits, you will also be contacted by phone on a weekly basis to check how you are doing.

If you are not discontinuing antidepressant and/or antipsychotic medication(s) during the screening period, you will visit the clinic weekly for a minimum of 2 weeks and up to 6 weeks before you receive COMP360 to ensure your safety.

On the dosing day, at the study clinic, you will take your 25 mg dose of COMP360 orally, at least 2 hours after a light breakfast, with a full glass of water to aid swallowing.

4 WHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in this research study, you will need to visit the study clinic up to 15 times within approximately 18 weeks, and 2 of these visits can be conducted by phone. In addition to this, during the screening period, you will be contacted by phone up to 5 times to check how you are doing in between each weekly screening visit. The first screening visit may last approximately 5 hours and subsequent screening visits may last up to 1 hour. The baseline visit may last approximately 5 hours and the dosing visit between 6 to 8 hours. Safety follow-up visits may last from 30 minutes to up to 3 hours (full details are provided in Section 4.1, Schedule of Assessments).

If you sign this informed consent form, you are agreeing to follow the instructions given by the study staff during the study. During all parts of the study, you will be assessed to monitor your health and the effects of the study treatment. It is important that you come to all study visits at the scheduled time. If you cannot attend at the scheduled time, please set up a new time as soon as possible by using the contact details for the study doctor on the first page.

Each study visit will include some or all of the following tests/procedures:

- **Qualifying Questions:** The study staff will ask questions to determine whether you qualify to be in this study, based on specific study requirements.
- **Demographic Questions:** The study staff will record your age, sex, race, and ethnicity (as response to treatment may vary between genders and different ethnic groups/races).

- **Medication and Treatment Review:** You will be asked about any medications or treatments you have taken in the past 30 days or are taking now, including prescription medications, over-the-counter medications, vitamins, herbal supplements, and natural remedies. Certain medications and treatments may not be allowed during the study. Throughout the study, you will be asked to report any changes in your medications or treatments. Some prescribed medications are permitted alone or in combination with others. Some of those prescribed medications should be avoided for 12 hours before and 6 hours after you receive COMP360. If you are taking any of these medications, the study doctor or study staff will discuss this with you.
- **Medical History Review:** You will be asked about any significant illnesses/conditions you have experienced over your lifetime and any illnesses/conditions you currently have. This includes confirmation of your PTSD.
- **Height and Weight Measurement:** At the start of the study your height and weight will be measured, and the measurements will be used to calculate your body mass index (BMI).
- **Vital Signs:** Your vital signs will be measured. This includes your blood pressure (how much pressure it takes to move your blood through your body), pulse (the number of heart beats per minute), respiration rate (the number of breaths per minute) and body temperature.
- **Electrocardiogram (ECG):** This is a non-invasive test that measures the electrical activity of your heart. You will be asked to lie down, and small sticky pads will be placed on your arms, legs, and across your chest.
- **Pregnancy Test:** If you are a female who is able to have children, a urine/blood pregnancy test will be performed. If you are unable to have children, this may be confirmed via a blood test or your medical history. You cannot take part in this research study if you are pregnant, breastfeeding, or planning a pregnancy.
- **Urine Drug Screen:** A urine sample will be taken at the first screening visit, the baseline visit, and at follow-up visits done in clinic to test for drugs of abuse (e.g., amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, and opiates). If you test positive for drugs of abuse at the screening or baseline visits, you may not be able to participate in this study. Your study doctor will discuss this with you.
- **Blood and Urine Sampling for Safety Testing:** Blood (approximately 65 mL or about 4 tablespoons) and urine samples (at the screening and baseline visits only) will be collected to assess whether you are able to participate in the study, to test for any infections or diseases, and to assess your general health throughout the study.
- **PTSD Assessments/Interview:** The study doctor will ask you about 30 questions about the type and severity of your PTSD symptoms and you will give your responses. You will also be asked to complete a questionnaire (about 20 questions) about your PTSD symptoms. For these assessments, you will be asked to rate your responses (e.g., 0 = not at all/absent and 4 = extremely/incapacitating). You will have a semi-structured interview with the study staff at the baseline visit only. During the interview, you will be asked questions about your PTSD symptoms, feelings when you were first diagnosed and the treatment and support you were offered before participating in this research study.
- **Trauma Assessments:** You will be asked to complete a 20-item scale to assess how you cope with trauma. You will also be asked to complete a life event checklist to screen for

potentially traumatic events that may have occurred in your lifetime, and you will be assessed for any childhood traumatic events such as child abuse and neglect.

- **Suicide Risk Assessment:** You will be asked some questions to determine how you are feeling emotionally, and whether you may be at risk of harming yourself or ending your life. At the screening visit, the questions will be based on how you have been feeling emotionally over the last 12 months. After the screening visit, the questions will be based on how you have been feeling since your last clinic visit. You will not be allowed to take part in this study if you are at risk for suicide.
- **Psychiatric Assessments/Interview:** You will be asked to complete a 10-item scale, and the study staff will ask you a set of structured questions to assess your psychological health.
- **Withdrawal of Medication Assessment:** If it is necessary for you to stop taking certain medications such as antidepressants or antipsychotics to take part in this study, you will be asked to complete a 15-item scale to assess how the withdrawal of the medication is affecting you. The scale will ask you to rate symptoms that might occur when you stop taking the medication.
- **Emotional Breakthrough Assessment:** You will be asked to complete an 8-item scale to measure your emotions, memories, and feelings during treatment.
- **Disability Assessment:** You will be asked to complete a scale to assess any functional problems you may have as part of your work, social and family life.
- **Resilience Assessment:** You will be asked to complete a 33-item scale to measure certain characteristics of resilience, such as how you perceive yourself and interact socially, as well as to assess your family health.
- **Quality of Life Questionnaire:** You will be asked to complete a questionnaire that asks questions about your mobility, ability to care for yourself, ability to perform normal daily activities, and if you are experiencing any pain, discomfort, or anxiety/depression.
- **Side Effect and Adverse Event Review:** You will be asked how you are feeling and to report any side effects or symptoms you may experience, while in the study. The study staff will monitor any changes in your health throughout the study.
- **Preparation:** You will meet with your assigned study therapists three times, twice during the screening period and once on the day before the study medication administration. These are called preparation sessions, where you will review psychoeducational material on COMP360, prepare for what to expect during the administration session, practice some relaxation techniques, and talk about how to best manage the range of experiences you might encounter during the study medication administration session. For all participants, preparation sessions will take place at the final two screening period visits and a final preparation session will take place at baseline. If you are discontinuing antidepressant and/or antipsychotic medication(s), you must have completed taking your previous medication(s) before the first preparation session. Your study therapist will be able to answer all the questions that you might have.
- **Study Medication Administration:**
  - The study medication administration visit usually takes between 6 to 8 hours. On the morning of the visit, you should have a light breakfast 2 hours before coming to the study clinic. At the study clinic, you will be given 5 capsules containing 5 mg of COMP360 to take with water to aid swallowing. After taking the study medication, you will be asked to lie down in a room with dim lights, and some relaxing music will

play quietly. Two trained therapists will be present with you at all times. The effects of COMP360 usually start around 30 minutes after taking the capsules, become most intense in the first 2 hours, then gradually subside. You will be asked to stay in the treatment room, preferably lying down, for the duration of the session regardless of the intensity of the effects. A light meal and fruit will be available for you.

- At the end of the session, your therapist will discuss the study medication experience with you, and you will be asked to complete a questionnaire to evaluate the effect of COMP360 and to assess your state of consciousness. When the study doctor confirms the effects of COMP360 have resolved, you can leave the study clinic. You will not leave the study clinic alone. The study team will call a taxi to take you home accompanied by a member of the study staff or a friend/relative can drive you home. In the case that a friend/relative is present, the site is to be notified that you have returned home safely, and in the absence of receiving a phone call, the site staff will directly contact you to make sure you arrived safely. If it is not possible for you to get home, overnight accommodation can be arranged close to the study clinic.

- **Integration:** During integration sessions, the study therapists will ask you some questions about your experience and discuss with you how you can integrate any insights from the study medication administration session into your everyday life. You will meet with your study therapist the day after, and one week after the study medication administration session for your integration sessions.
- **Video and Audio Recording (Optional):** If you agree, your treatment session will be recorded (both video and audio), and all interactions with the study staff will be audio recorded. The Sponsor intends to use these recordings for research, adherence monitoring, and quality assurance. If you agree, we may also use the information collected about you to support other research in the future. The video and audio recordings are optional, and you will only be recorded if you provide your consent at the end of this form.
- **Study Treatment Interview:** You will be asked some questions and to give your overall opinion of your experience with COMP360 treatment.
- **Cue™ App (Optional):** HealthRhythms' smartphone application (app) called Cue™ uses smartphone sensors to automatically detect behavior patterns, or rhythms, as you go about your daily life. These rhythms can provide helpful insights as to how you as an individual are responding to the treatment in this research study. If you decide to participate in the Cue™ part of this research study, an app will be installed on your smartphone at the screening visit; and uninstalled at the end of the study. The Cue™ app will continuously run in the background on your phone and collect data, which will periodically be sent to HealthRhythms' secure servers. Once the app is installed on your phone, you will not need to do anything: continue using your phone as you would normally and keep it with you as often as possible. Using the Cue™ app is optional, and you will only be asked to do this if you provide your consent at the end of this form.
- **Blood Sampling for Biomarker Testing and Blood Banking (Optional):** Blood samples (a maximum of 300 mL or about 20 tablespoons over 3 study visits) will be collected for biomarker testing. Biomarkers are specific markers or characteristics associated with a condition or a response to treatment. They can be specific cells, genes, proteins, or hormones, etc. In addition, some of the samples will be banked (saved) for

future studies. This assessment is optional, and your samples will only be collected and assessed if you provide your consent in a separate form.

- **Magnetic Resonance Imaging (MRI) Scan (Optional):** If you decide to participate in the optional brain imaging, you will have 2 MRI scans. MRI scans use a magnetic field and radio waves to take images of parts of the body. In this study, the activity of areas of your brain will be monitored in response to some trauma or emotional tasks. This assessment is optional. The study doctor will discuss this option with you. You will only be asked to take part in the optional MRI (brain imaging) if you provide your consent.

Any companions you have (carers/friends/family) may receive information about the signs of worsening PTSD and suicide risk and ways to contact the study team, if necessary.

4.1 Schedule of Assessments

Assessments/ Tests	Screening Period		Baseline	Dosing Day	Safety Follow-up Period						
Visit	1	1a, 1b, etc	2	3	4	5	6	7	8	9	10 (ET)[2]
Visit Timing	From 3 to 6 weeks before treatment	Weekly visits[1] (from 2 to up to 6 weeks before treatment)	Day before treatment	Day 1 (Dosing Day)	Day 2	Week 1	Week 2	Week 4	Week 6	Week 9	Week 12
Location of Visit	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Home/ Study Clinic	Home/ Study Clinic	Clinic
Approx. Duration	3.5 – 5 hours	Approx. 1 hour	4 – 5.5 hours	6 – 8 hours	1.5 – 2 hours	1 – 1.5 hours	1 – 1.5 hours	2 – 3 hours	30 – 45 minutes	30 – 45 minutes	2 – 2.5 hours
Approx. Volume of Blood Collected (mL)	13	0	13/(100)[3]	0	13	0	0	13/(100)[3]	0	0	13/(100)[3]
Informed Consent	✓										
Qualifying Questions	✓		✓								
Demographic Questions	✓										
Medication and Treatment Review	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Medical History Review	✓		✓								
Height and Weight Measurement	✓										
Vital Signs	✓		✓	✓	✓						
ECG	✓		✓		✓						

Assessments/ Tests	Screening Period		Baseline	Dosing Day	Safety Follow-up Period						
Visit	1	1a, 1b, etc	2	3	4	5	6	7	8	9	10 (ET)[2]
Visit Timing	From 3 to 6 weeks before treatment	Weekly visits[1] (from 2 to up to 6 weeks before treatment)	Day before treatment	Day 1 (Dosing Day)	Day 2	Week 1	Week 2	Week 4	Week 6	Week 9	Week 12
Location of Visit	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Home/ Study Clinic	Home/ Study Clinic	Clinic
Approx. Duration	3.5 – 5 hours	Approx. 1 hour	4 – 5.5 hours	6 – 8 hours	1.5 – 2 hours	1 – 1.5 hours	1 – 1.5 hours	2 – 3 hours	30 – 45 minutes	30 – 45 minutes	2 – 2.5 hours
Approx. Volume of Blood Collected (mL)	13	0	13/(100)[3]	0	13	0	0	13/(100)[3]	0	0	13/(100)[3]
Pregnancy Test[5]	✓		✓		✓						
Urine Drug Screen[6]	✓		✓		✓	✓	✓	✓	✓	✓	✓
Blood and Urine Sampling	✓		✓		✓[4]			✓			✓
PTSD Assessments/ Interview	✓		✓		✓	✓	✓	✓	✓	✓	✓
Trauma Assessments	✓		✓					✓			✓
Suicide Risk Assessment	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Psychiatric Assessments/ Interview	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
Withdrawal of Medication Assessment		✓	✓								

Assessments/ Tests	Screening Period		Baseline	Dosing Day	Safety Follow-up Period						
Visit	1	1a, 1b, etc	2	3	4	5	6	7	8	9	10 (ET)[2]
Visit Timing	From 3 to 6 weeks before treatment	Weekly visits[1] (from 2 to up to 6 weeks before treatment)	Day before treatment	Day 1 (Dosing Day)	Day 2	Week 1	Week 2	Week 4	Week 6	Week 9	Week 12
Location of Visit	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Home/ Study Clinic	Home/ Study Clinic	Clinic
Approx. Duration	3.5 – 5 hours	Approx. 1 hour	4 – 5.5 hours	6 – 8 hours	1.5 – 2 hours	1 – 1.5 hours	1 – 1.5 hours	2 – 3 hours	30 – 45 minutes	30 – 45 minutes	2 – 2.5 hours
Approx. Volume of Blood Collected (mL)	13	0	13/(100)[3]	0	13	0	0	13/(100)[3]	0	0	13/(100)[3]
Emotional Breakthrough Assessment					✓						
Disability Assessment			✓					✓			✓
Resilience Assessment			✓					✓			✓
Quality of Life Questionnaire			✓					✓			✓
Side Effect and Adverse Event Review	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Preparation		✓	✓								
Study Medication Administration				✓							
Integration					✓	✓	✓				

Assessments/ Tests	Screening Period		Baseline	Dosing Day	Safety Follow-up Period						
Visit	1	1a, 1b, etc	2	3	4	5	6	7	8	9	10 (ET)[2]
Visit Timing	From 3 to 6 weeks before treatment	Weekly visits[1] (from 2 to up to 6 weeks before treatment)	Day before treatment	Day 1 (Dosing Day)	Day 2	Week 1	Week 2	Week 4	Week 6	Week 9	Week 12
Location of Visit	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Study Clinic	Home/ Study Clinic	Home/ Study Clinic	Clinic
Approx. Duration	3.5 – 5 hours	Approx. 1 hour	4 – 5.5 hours	6 – 8 hours	1.5 – 2 hours	1 – 1.5 hours	1 – 1.5 hours	2 – 3 hours	30 – 45 minutes	30 – 45 minutes	2 – 2.5 hours
Approx. Volume of Blood Collected (mL)	13	0	13/(100)[3]	0	13	0	0	13/(100)[3]	0	0	13/(100)[3]
Medication Effect and Consciousness Assessment				✓							
Study Treatment Interview					✓						✓
Cue™ App (Optional)	✓										✓[4]
Blood Sampling for Biomarker Testing and Blood Banking (Optional)			✓					✓			✓
MRI Scan (Optional)			✓[7]					✓			

[1]During screening period, in between each in-person weekly visit, you will be contacted on the phone to check your welfare.
[2]ET = Early Termination Visit.
[3]Volume of blood collected for optional biomarker testing and blood banking.

[4]Cue™ app removed from smartphone.
[5]Serum pregnancy test at screening visit and urine pregnancy test on the day before treatment (Visit 2/baseline) and on Day 2 (Visit 4).
[6]If the test results are positive at the screening visit, Day 2, or Weeks 1 to 12, the result will be confirmed by further analysis of the sample. If the study visits at week 8 and week 9 are done at home, urine drug screening may not be needed.
[7]The MRI scan at Visit 2/baseline can take place up to 7 days before Visit 2/baseline.

Please Note: In the case of vaccination for COVID-19 during study participation, please let the study staff know immediately about the date of vaccination or plans for it. Vaccination is not mandatory, and your vaccination status will not affect your participation in this study.

5 WHAT WILL I BE EXPECTED TO DO WHILE IN THE STUDY?

Taking part in a research study can be an inconvenience to your daily life. Please consider the study time commitments and responsibilities as a research participant when you are deciding to take part. Your responsibilities as a study participant may include the following:

- Telling the study doctor about your medical history and current conditions, and if necessary, this includes the time after the study ends/is halted and until any side effects disappear.
- Agreeing to be contacted by the study team as necessary, by telephone or in writing.
- Telling the study doctor if you have been in a research study in the last 30 days or are in another research study now.
- Coming to all study visits on time.
- Planning the dates and times of your visits well in advance.
- Telling the study doctor about any problems you have during the study.
- Following rules about any medicines that you should not take while in this study. The study doctor or study staff will talk to you about these.
- Not driving or using machinery for a period of 24 hours after taking your study medication.
- Contacting the study team as soon as you arrive home following your study medication session.
- Making sure you follow government advice for COVID-19 (eg, travel limitations, social distancing) and informing your study doctor in case you have planned or received a COVID-19 vaccination during your participation in this study.
- Making sure you carry the study card that has details of this study at all times.
- Informing the study team as soon as possible if you (female participants or the partner of a male participant) become pregnant during the study.
- Telling the study doctor if you wish to withdraw from the study before its planned completion and coming to the study clinic for an Early Termination Visit (Visit 10). You should follow any instructions given to you during this visit. Your part in the research study may also end at any time for any reason, even if you do not want to stop participating.

6 RISKS AND DISCOMFORTS OF THE STUDY

Side Effects of Active Study Medication (COMP360)

The investigational study medication COMP360 is at a research stage, so it may have side effects that are not known at this time. As with any new medication, there is a risk that unexpected adverse effects may occur. Almost all medications, both old and new, can cause severe reactions. At least 500 research participants have received COMP360. In previous research studies of COMP360 in humans, participants received COMP360 at doses of up to 25 mg, and the vast majority of them tolerated it well.

After taking COMP360, you may experience some of the effects described below. In general, these effects are mild or moderate and typically last no more than 24 hours:

Very common: may occur in more than 1 in 10 people

- Anxiety and panic response (this can happen right at the beginning, but tends to ease quickly)
- Headache (this may last for a couple of days)
- Nausea and dizziness
- Back pain
- Tiredness and sleepiness
- Increased blood pressure and heart rate (your heart may pump harder and faster for a few hours, but not more than it would if you were anxious or had just done some exercise)
- Hallucinations (you may see things, hear sounds, and feel bodily sensations that are not real)
- Sensory distortions (the way you perceive things through the sense could be distorted)
- Synesthesia (eg, the sounds you hear may trigger you to see different colours)
- Abnormal skin sensations (eg, tingling, prickling, changes in the perception of temperature)
- Hyperesthesia or hypoesthesia (your skin and body sensations may be slightly increased or decreased)
- Derealisation (your surroundings may feel unreal, you may temporarily lose the sense of who you are, and you may lose the track of time)
- Mood changes (you may feel relaxed and positive, or you may feel sad and mournful)
- Intense feelings of well-being and happiness

Uncommon: may occur in 1 to 10 in 1000 people

- Upsetting thoughts.
- "Flashback," or hallucinogen-induced persistent perceptual disorder (HIPPD). This adverse effect has been seen, rarely, following recreational use and in scientific studies.
- Reckless behaviour.

As the safety, tolerability, and effectiveness of COMP360 are still being researched, there is no guarantee that it will be effective for you. Your symptoms may not improve or may even worsen.

Suicidal Ideation and Behaviour

Although uncommon, you might experience an increase in suicidal thoughts after COMP360 administration. This was observed in about 6% of people with treatment-resistant depression who had COMP360 psilocybin therapy in a large research study. If you notice the onset or worsening of suicidal thoughts or are considering taking actions upon your suicidal thoughts, please immediately contact emergency services and go to the nearest hospital emergency department. You should also contact your study team immediately. If the study team has any concerns about your safety from the assessments conducted during the study visits with you, they would be obliged to involve local health services to determine how best to support you. You will be given a "contact card" providing the contact details for the key members of the study team during office hours. You will also be provided with an out-of-hours emergency contact number for a member of staff who has awareness of the study.

There are also support services available that you may find helpful, such as *[Adapt according to local practices eg., the Samaritans – a 24-hour phone line offering emotional support]*.

Allergic Reactions

There have not been any reports of allergic reactions with COMP360. However, as with any medication, there may be a risk of allergic reaction. In very rare cases, a serious allergic reaction can be fatal. Some symptoms of an allergic reaction are: shortness of breath/wheezing, itchy rash (hives) or swelling, flushing (feeling warm), low blood pressure, fast heart rate, confusion, anxiety, feeling light-headed or faint, sweating and clammy skin.

Hallucinogenic Persistent Perception Disorder (HPPD)

The active ingredient of COMP360 is psilocybin, which is a psychedelic substance. People who take psychedelics may very rarely develop HPPD, a condition that may last for years. It is estimated that 1 in 50,000 people who are frequent users of psychedelics end up having HPPD.

There are 2 types of HPPD. Sometimes it consists of recurring flashbacks from the psychedelic experience. The other type of HPPD consists of visual distortions that make colours appear more intense or blurred, objects appear as having a shiny halo or a less defined and distorted outline. Images can be perceived as having trails. Straight lines can become wiggly and have a yellowy tinge.

Blood Sampling

To take blood from you, a needle will be inserted into your vein. The risks of taking blood include fainting and pain, bruising, swelling, or rarely, infection where the needle was inserted.

Electrocardiogram

The sticky pads placed on your skin for the ECG may sometimes cause some skin irritation, such as redness or itching.

Magnetic Resonance Imaging (MRI) Scan (optional)

When an MRI scan is performed, you are not exposed to radiation. However, a strong magnetic field can attract objects made from certain metals. Inform the study staff if you have metallic implants, a cardiac pacemaker, a prosthetic heart valve, or shrapnel. You should follow the instructions provided to you before your MRI scan.

Risks to an Unborn Child

Women

You may not take part in this study if you are breastfeeding, pregnant, think that you may be pregnant, or are trying to get pregnant. If you are pregnant or breastfeeding, there may be risks to you and your child that are not known at this time. Taking COMP360 may harm an unborn child.

To take part in this research study you must either be: post-menopausal (for 1 year or longer), surgically sterile, or willing to use a highly effective method of contraception for the duration of the study. Acceptable contraceptive methods include:

- Combined (estrogen and progestogen containing) hormonal contraception (eg, oral pills or transdermal patches)
- Progestogen-only hormonal contraception (eg, oral pills, injectable or implantable)
- Intrauterine device
- Intrauterine hormone-releasing system
- Bilateral tubal occlusion
- Vasectomised partner
- Sexual abstinence – only acceptable when refraining from heterosexual intercourse during the entire period of the study and when in line with your preferred and usual lifestyle

Periodic abstinence (e.g., calendar, symptothermal, or post-ovulation methods) is not an acceptable form of contraception for this study.

It is important for you to tell the study doctor immediately if you get pregnant or think that you might be pregnant while you are in the research study. The study doctor may ask for your permission to collect information regarding the pregnancy and its outcome.

Men

COMP360 may harm an unborn child. To take part in this research study you must either be: surgically sterile, willing to abstain from heterosexual intercourse, or you must inform your female partner of your participation in this study and you must both agree to use a highly effective method of contraception. You must use a condom for the duration of the study. Your partner must use a contraceptive method as listed above.

If you think that your partner has become pregnant, you, in agreement with your partner, must tell the study doctor immediately. The study doctor may ask permission from your partner to collect information regarding the pregnancy and its outcome.

Unknown Risks

There may be risks to you that are currently not known or cannot be predicted. Your condition may worsen, remain the same, or improve as a result of participating in this research study. Please seek treatment immediately and tell the study doctor and study staff if you have any of the symptoms mentioned in this section, or any other side effects, during the study (even if you think

they are not related to your participation in this study). You might have side effects or discomforts that are not listed in this section. Some side effects may not be known yet. New ones could happen to you.

7 DO I NEED TO PARTICIPATE IN THIS STUDY TO RECEIVE TREATMENT FOR MY CONDITION?

You do not need to take part in this research study to receive treatment for PTSD. There are other treatments for PTSD.

Your study doctor can discuss these alternatives and the risks and benefits of these alternatives with you.

8 ARE THERE ANY BENEFITS TO BEING IN THE STUDY?

You may or may not receive any benefit from being in the study. It is possible that you may get better, stay the same, or get worse. If you take part in this study, other people with PTSD may be helped by the research.

9 WILL IT COST ME ANYTHING, AND WILL I BE PAID TO BE IN THE STUDY?

The study medication and all tests and procedures required by the study are provided at no cost to you. The Sponsor will pay for them. The costs of other medications and treatments that you take or use independently of the study are not covered by the Sponsor.

You will not be paid for being in this study. Reasonable expenses (e.g., travel) will be reimbursed, after receipts for the payments are provided, and in agreement with the study doctor.

10 DOES THE DOCTOR GET PAID FOR CONDUCTING THE STUDY?

The Sponsor is paying the study doctor and study staff for their work in this study.

11 WHAT IF I AM INJURED DURING THE STUDY?

If your health is impaired or you suffer any injury or side effects during or after the research study, please contact the study doctor responsible for this study (contact details are on the first page). The study doctor will begin the necessary steps for you. If you are harmed or become sick as a direct result of taking the study medication or the study procedures, medical treatment will be offered to you by the Sponsor. The Sponsor will compensate you for medical and other related treatment costs that occur directly as a result of the research study only. For this purpose, the Sponsor has taken out an appropriate insurance in your favour with Newline Underwriting Management Limited, Corn Exchange, 55 Mark Lane, London, EC3R 7NE.

By signing this form, you do not waive any rights to pursue personal injury claims.

[US sites] Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information. You will be responsible for

any injury-related costs that are not covered by your insurance or paid for by the Sponsor (as described above).

12 WILL MY PERSONAL DATA/PROTECTED HEALTH INFORMATION BE KEPT CONFIDENTIAL?

Collection and processing of personal data/protected health information for the research study:

Your personal data/protected health information will be processed and shared during the study by your study doctor, study staff, and representatives/designees of the Sponsor for the following purposes:

1. Reliability and Safety Purposes: Your personal data/protected health information will be processed in order to ensure that study data is reliable and that safety requirements have been met for your participation in the study.

2. Research Activity Purposes: Your personal data/protected health information will be processed for scientific research purposes related to the safety and tolerability of COMP360 in participants with PTSD.

[WHERE GDPR IS IN SCOPE] The legal bases for processing and sharing your personal data for the purposes mentioned above are:

1. Reliability and Safety Purposes: For personal data, the legal basis is the Sponsor's compliance with a legal obligation under the national law implementing ICH-GCP (GDPR Article 6(1)(c)). For sensitive personal data, the legal basis is that processing is necessary for reasons of public interest in the area of public health (GDPR Article 9(2)(i)).

2. Research Activity Purposes: For personal data, the legal basis is the Sponsor's legitimate interests (GDPR Article 6(1)(c)). For sensitive personal data, the legal basis is that processing is necessary for scientific research purposes (GDPR Article 9(2)(j) and Article 89(1)). For personal data collected for optional procedures and assessments, the legal basis is your consent (GDPR Article 6(1)(c)). For sensitive personal data collected for optional procedures and assessments, the legal basis is your explicit consent (GDPR Article 9(2)(a)).

What personal data/protected health information will be used and disclosed?

For the purposes mentioned above, the Sponsor and the study doctor may use the following personal data/protected health information:

- Identification data: name, gender, ethnicity, address, date of birth, identification code (participant code), contact number, and email address
- Unique participant identification number

The Sponsor and study doctor will also use the following sensitive personal data/protected health information:

- Biological samples (e.g., blood and urine samples)
- Scans and the results of their evaluation
- Demographic data

- Video recordings of your treatment sessions, and audio recordings of certain interactions with the study staff
- Cue™ app data
- General information relating to your health condition

Who are the authorised recipients of your personal data/protected health information?

- Sponsor or persons working on behalf of the Sponsor (eg, representatives of Sponsor, monitors and auditors of the Sponsor, or representatives of Worldwide Clinical Trials or ICON, the contract research organisation working with the Sponsor on this study)
- The study doctor and study staff
- Independent Ethics Committees
- Regulatory authorities, such as the FDA, MHRA, other US or UK governmental agencies, or the European Medicines Agency (EMA)
- Other government agencies (including those outside of your country of residence)
- Laboratories working with the Sponsor on this study
- Vendors working on this study
- Individuals involved in obtaining marketing authorisation for the study medication
- Service providers who assist in managing, administering, or delivering reimbursement services
- Your regular health care provider (for safety)

[US sites only] You should also inform your insurance provider of your participation in this research study.

How will my personal data/protected health information be processed?

The study doctor and team, and representatives/designees of the Sponsor will process and use your personal data/protected health information collected during the research study and during the screening period. Your personal data/protected health information will be collected via study forms that will include additional information relating to your health and medication history, the results of examinations, and tests completed during the research study.

At the end of the screening period, you will be assigned a unique participant identification number. This unique participant identification number will be used to identify you on study forms, and you will not be identified on any study form by name or other personal information. Any personal data/protected health information processed outside of the study clinic will only refer to you by your unique participant identification number. Decoding will only take place as required by law.

While at the study clinic, the study doctor and staff, and designees/representatives of the Sponsor will have direct access to the directly identifiable personal data/protected health information collected to ensure they are correct and that the study was conducted properly (monitoring and auditing purposes). The study staff will use your name and contact details to contact you about the research study (eg, visit reminders or follow-up purposes), make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

You may also be contacted after the study has ended to inform you of the study outcome. The study staff may also need to correct or provide missing information about you even after your study participation is over and review of your medical records may also take place after the study is over.

[WHERE GDPR IS IN SCOPE] COMPASS Pathfinder Limited is the Sponsor of the study and as such, will act as data controller with respect to the research data/records (except for your medical records used for standard care purposes) and the conduct of the study. *[study centre name]* is the controller of your medical records retained on site. This means that the Sponsor and *[study centre name]* are both responsible for safeguarding your personal data collected during your participation in the study and for using it properly.

[UK Sites] The Sponsor will keep your study records for up to 15 years after the study has been finalised, or longer if required by applicable law and/or clinical guidelines.

[US Sites] If no marketing application is to be filed or if the application is not approved, protected health information will be stored for 2 years after the study has concluded, or longer if required by applicable law and/or clinical guidelines.

Specific data uses:

Biological Samples: Biological samples taken during the study will be labelled with the study number, information related to the sample, the sample date, and the participant code. The "key" that links this code with your unique participant identification number will be kept at the study clinic together with your medical records for as many as 15 years, or more, after the trial has been finalised, in compliance with applicable laws. Access rights to this key are only granted to authorised personnel. It is not possible to trace any personal data/protected health information back to you without this key. Decoding will only take place as required by law. No directly personal identifiers (such as your name or date of birth) will be recorded on the sample labels. The Sponsor must follow applicable laws and regulations, and all collected information will be coded so that no individual persons can be identified during analysis of data. Your samples will be stored and analysed at ACM Global Laboratories, [redacted] Blood and urine samples for routine analysis are destroyed after testing.

Video and Audio Recordings: The recordings may be used by the Sponsor for research, adherence monitoring, study staff training, and quality assurance purposes. In the video recording, your face will be redacted (hidden/covered up) to protect your identity. The Sponsor, contractors, and/or consultants may see the unredacted video recording for your safety or in order to perform technical processing of the recording.

Any recorded material would be stored securely by the Sponsor in accordance with the applicable US and UK Data Protection law. The Sponsor would have access to your recordings. Sponsor personnel include, but are not limited to, employees, consultants, contractors, and other agents working on behalf of COMPASS Pathfinder Limited.

You may ask that we do not video record the session or stop recording at any time during the session, and that would be fine. You may request your original recorded material to be destroyed (via deletion of digital files) at any time. This will not affect your participation in the study.

Cue™ App: The data collected from your phone will include GPS location (to measure social engagement as reflected in time spent at home versus in other locations), pedometer data (to measure physical activity including step count and walking rate), and your screen on/off times (to measure phone usage and sleep cycles). Cue™ does not collect data from texts, calls, photos, internet browsing, or other apps on your phone. No personally identifiable information (eg, the actual location of your home or place of work or other places you may visit) is saved, and all captured data are encrypted and de-identified before being uploaded to HealthRhythms' cloud storage servers. The data remain encrypted in transit and at rest. The application will be uninstalled at the last study visit or sooner if you choose to withdraw from the study earlier.

You may request that your Cue™ data be destroyed (via deletion of digital files) at any time. This will not affect your participation in the study.

Registries and Publications: A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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 website at any time.

A description of this clinical study will be available on http://www.ClinicalTrials.gov and the European Union Medication Regulating Authorities Clinical Trials Database as required by UK/European laws. These web sites will not include information that can identify you. At most, the website will include a summary of the results. You can search these web site at any time.

The results of the study will be submitted to one or more Sponsor offices, health/regulatory authorities, qualified third-party researchers, and other approving bodies. The results may also be presented at meetings or published in medical journals. You will not be identified in any presentation or publication resulting from the study.

Regulatory Authorities: The regulatory authorities will be granted direct access to your original study records in order to audit, monitor, and verify the proper conduct of the study, evaluate study results and adverse events, and provide approval/marketing authorisation.

Will my personal data/protected health information be shared?
[WHERE GDPR IS IN SCOPE] Your personal data will only be shared with and disclosed to authorised third parties and recipients, if instructed and permitted by the Sponsor. Some of those third parties and recipients might be located outside your country of residence and/or the UK, where the level of protection of personal data information might not be as strict and advanced as in your country and may not stop coded study data from being shared with others. A transfer of personal data outside the UK may pose a security risk, as well as the risk that you may not be able to exercise certain rights, or may have more difficulty exercising such rights, in respect to these recipients. In those cases, your personal data will only be transferred where appropriate safeguards are in place to it (such as UK Standard Contractual Clauses). You can find more

information on these safeguards by contacting the study doctor (using the contact details on the first page), who will contact the Sponsor's data protection officer as needed.

[WHERE GDPR IS NOT IN SCOPE] Your protected health information may be further shared by the authorised recipients above. Once your protected health information has been shared with authorised recipients, it may no longer be protected by Federal privacy law/*[state applicable law for non-US sites]*. Using and sharing protected health information about you will not end unless required by state law.

All third parties and recipients are obligated to observe the rules of professional confidentiality and will only use your personal data/protected health information for the purpose of the study and as described in this section.

What are my rights?

[WHERE GDPR IS IN SCOPE] You have the right to access personal data and correct inaccurate personal data processed in the study. You may also have the right to erase, limit, or object to the processing of your personal data (including your biological samples), where such processing is a) no longer necessary for the purposes described in this section, or b) is processed only for scientific research purposes, and the Sponsor does not have compelling legitimate grounds to continue processing when it overrides your interests, rights, and freedoms. You can exercise your rights by contacting the study doctor (using the contact details on the first page), who will contact the Sponsor's data protection officer as needed.

You also have the right to lodge a complaint regarding how your personal data are being handled, with the supervisory authority responsible for enforcing data protection legislation *[Insert contact information for local supervisory authority here]*.

[WHERE GDPR IS NOT IN SCOPE] You have the right to review and copy your protected health information. However, your access to this information may be delayed until the study is complete. You may have the right to request your protected health information to be deleted (including destruction of your biological samples). You can exercise your rights by contacting the study doctor (using the contact details on the first page). However, in some instances, such as complying with FDA regulations, the Sponsor may be required to retain your personal health information until the study is completed, even if you request it to be deleted.

Withdrawal:

If you wish to withdraw your consent to participate in the research study, no further personal data/protected health information will be collected about you unless it is necessary for your safety or to maintain the integrity of the research. The Sponsor may, however, still use your personal data/protected health information that was collected and shared before you withdrew your consent, as described in this form. If you wish to withdraw from the research study, you must notify the study doctor using the contact details on the first page.

Organisational and technical safeguards:

The Sponsor and study clinic have put in place appropriate security measures to prevent your personal data/protected health information from being accidentally lost, used, altered, disclosed, or accessed in an unauthorised way. Specifically, your personal data/protected health information will be coded or "pseudonymised" before it is stored, analysed, or transferred. The Sponsor and study clinic have also put in place procedures to deal with any personal data/protected health information breach and will notify any applicable regulator of a breach as required by law. Furthermore, your study doctor will inform you of any personal data/protected health information breach as required by law.

13 IS BEING IN THE STUDY COMPLETELY VOLUNTARY?

Entering a research study is completely voluntary. Your part in the research may stop at any time for any reason, such as:

- The Sponsor or the study doctor decides to stop the study.
- The Sponsor or the study doctor decides to stop your participation in the study for your safety.
- You need additional medicine that is not permitted in this study.
- You (females only) become pregnant.
- You do not follow the study rules.
- Your condition becomes worse.
- You have a new injury or illness.
- You decide to stop.

The Sponsor may decide to stop the study at any time. You may be asked to stop being a participant in the research study even if you do not want to stop.

14 WILL I BE CONTACTED AGAIN FOLLOWING COMPLETION OF THE PRESENT STUDY?

With your consent, we would like to contact you again for any further research-related to the study and the development of COMP360 therapy, which may or may not take place in the future. If you do give your consent for further contact (by giving your consent at the end of this form) but, decide later that you do not want to be contacted again, you may opt out when we contact you, and we will not contact you again.

STATEMENT OF CONSENT

I have read this informed consent form, and its contents were explained to me. I have had the opportunity to ask questions and all my questions were answered to my satisfaction. I agree to be in this research study for the purposes listed above. I understand that my participation in this study is voluntary and that I am free to withdraw at any time and without giving a reason. I will receive a signed and dated copy of this informed consent form for my records. I am not giving up any of my legal rights by signing this form.

Please check 1 box below:

I agree ☐/I do not agree ☐ that my regular health care provider may be advised of my participation in this research study.

I agree ☐/I do not agree ☐ to the MRI scans as described in this informed consent form under Section 4.

I agree ☐/I do not agree ☐ to participate in the Cue™ application using my smartphone as described in this informed consent form under Section 4.

I agree ☐/I do not agree ☐ to have my COMP360 session video recorded, including personal data on my health, for the purposes described in this informed consent form under Section 4. I understand that this includes audio (sound).

I agree ☐/I do not agree ☐ to have my interactions with the study staff audio recorded, for the purposes described in this informed consent form under Section 4.

I agree ☐/I do not agree ☐ that the information collected about me from the video and/or audio recording may be used in the future, to support further research. I understand that my anonymised information may be shared with other researchers, contractors, and consultants.

I agree ☐/I do not agree ☐ to be contacted by a member of the study team about any further research that may be of interest or benefit to me.

☐ I understand that if I withdraw from the optional procedures, the Sponsor will communicate this to all recipients and processors of my personal data/protected health information. In that case there will be no further data collection by means of the Cue™ application and/or audio recordings and/or video recordings. However, my personal data/protected health information previously collected by the Cue™ application and/or audio recordings and/or video recordings may continue to be used unless I specifically revoke my consent to process my personal data/protected health information. I understand that I may revoke this consent at any time, in which case previously collected data will be destroyed.

Signature of Research Participant | Date

Printed Name of Research Participant

The participant has indicated that he/she is physically unable to sign. The participant's consent has been obtained verbally by the study doctor (or authorised designee). The verbal consent process was overseen by an impartial witness.

Signature of Impartial Witness | Date

Printed Name of Impartial Witness

Impartial Witness: A person, who is independent of the study (eg, not a member of the study staff or a representative of the Sponsor), who cannot be unfairly influenced by people involved with the study, and who attends the informed consent process if the participant cannot sign.

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the participant the nature and purpose of the above study. There has been an opportunity for the participant to ask questions about this research study. I have been available to answer any questions the participant has about this study.

Signature of Person Explaining Consent | Date

Printed Name of Person Explaining Consent

Health Insurance Portability and Accountability Act (HIPAA) Authorization Agreement

Permission to Review, Use, and Release Information About You

If you decide to be in this study, the study doctor and research team will use and share protected health information about you to conduct the study, as described in Section 12. Please note that once your health data have been shared with authorized users, they may no longer be protected by Federal privacy law. If you do not sign this HIPAA Authorization Agreement, you will not be able to participate in the study. This authorization does not have an expiration date.

You may take back your permission to use and share protected health information about you at any time by writing to the study doctor. If you do this, you will not be able to stay in this study. No new data that identifies you will be gathered after your written request is received unless it is necessary for your safety or to maintain the integrity of the research. However, protected health information 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 personal health information in the study records will be suspended during the study to keep the study results from changing. When the study is over, you can access your study health data.

HIPAA AUTHORIZATION AGREEMENT

I confirm that I have read "Section 12 - Will my protected health information be kept private?" and its contents were explained to me. I have had the opportunity to ask questions and all my questions were answered to my satisfaction. I understand that my protected health information will be collected, used, and shared 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.

Signature of Research Participant	Date
Printed Name of Research Participant	

The participant has indicated that he/she is physically unable to sign. The participant's consent has been obtained verbally by the study doctor (or authorized designee). The verbal consent process was overseen by an impartial witness.

Signature of Impartial Witness | Date

Printed Name of Impartial Witness

Impartial Witness: A person, who is independent of the study (e.g., not a member of the study staff or a representative of the Sponsor), who cannot be unfairly influenced by people involved with the study, and who attends the informed consent process if the participant cannot sign.

STATEMENT OF PERSON EXPLAINING AUTHORIZATION

I have carefully explained to the participant the nature and purpose of this form. I have been available to answer any questions the participant has about this form.

Signature of Person Explaining Authorization | Date

Printed Name of Person Explaining Authorization

DATA PROTECTION

I confirm that I have read "Section 12 - Will my personal data be kept private?" and its contents were explained to me. I have had the opportunity to ask questions and all my questions were answered to my satisfaction. I understand that my personal data will be collected, used, and shared for the purposes 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.

Signature of Research Participant | Date

Printed Name of Research Participant

The participant has indicated that he/she is physically unable to sign. The participant's consent has been obtained verbally by the study doctor (or authorised designee). The verbal consent process was overseen by an impartial witness.

Signature of Impartial Witness | Date

Printed Name of Impartial Witness

Impartial Witness: A person, who is independent of the study (e.g., not a member of the study staff or a representative of the Sponsor), who cannot be unfairly influenced by people involved with the study, and who attends the informed consent process if the participant cannot sign.

STATEMENT OF PERSON EXPLAINING AUTHORISATION

I have carefully explained to the participant the nature and purpose of this form. I have been available to answer any questions the participant has about this form.

Signature of Person Explaining Authorisation | Date

Printed Name of Person Explaining Authorisation