Supplementary Materials

OPERATIONAL PROTOCOL: PARTICIPANT MANAGEMENT IN EXPERIMENTAL SESSIONS WITH HALLUCINOGENS IN CLINICAL RESEARCH

Objectives

• Ensure the safety and mental and psychological well-being of the participants using hallucinogenic substances in the context of clinical research;

• Provide guidelines for the assessment and management of the participant under the effects of classical hallucinogens (verbal measures and environmental management);

• Standardize the care provided by the professionals participating in the management of the volunteer;

Application Field

Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto (FMRP-USP); Department of Neuroscience and Behavioral Sciences, Mental Health Program (FMRP-USP)

Procedures

Screening

- Contact the potential participant and, in case of interest, provide a detailed explanation of the study protocol;
- After obtaining informed consent, perform a pre-screening interview (Annex 1) and record the data in clinical research patient record;
- If detected any exclusion criteria, the volunteer must be discharged at this moment;
- If the volunteer is using medications that must be withdrawn, inform them they must start the washout only after the screening process is completed and the subject is included in the study and they must not suspend any medication without medical supervision in any way;
- In case the volunteer satisfies the selection criteria and is willing to participate in the trial, the pre-screening record must be followed by the professional in charge of conducting the health screening;
- Perform the health screening using validated tools (like the SCID-V), in person or via teleconsultation, and record the data in clinical research medical record (psychologist or psychiatrist);
- If detected any exclusion criteria or any feature may pose a risk to the participant inclusion, the volunteer must be informed about their unsuitability and be discharged at this moment;
- If the patient meets all the selection criteria and has no health concerns, they must be referred back to the main investigator with their pre-screening and screening records.

Pre-Session

- Schedule the experimental session in advance and communicate with the staff
- If the volunteer is using medications that must be withdrawn, inform them they can start the washout at this point, under medical supervision (their attending doctor or research team's psychiatrists);
- Inform the participant they must refrain from using alcohol and other psychoactive substances before the experimental session;
- Inform the participant they must refrain from using tobacco and caffeine in the morning of the experimental session;
- As the participant arrives at the place, the staff must request the signing of an informed consent for participation in the study;
- Provide a standardized breakfast (crackers, cream cheese, fruit jams, butter and orange juice);
- Perform drug testing (alcohol, cannabis, cocaine) and pregnancy test (for women). In case of positive results, the participant is excluded from the study. Record the data in the clinical research patient record and dispose of the samples in appropriate places;
- Start the experimental session according to the study protocol.

Setting Management

- Before the start of the session, organize the experimental environment to ease the management in urgent situations: remove all objects that may be harmful either to the volunteer or to others, ensure that the personnel have easy access to the volunteer and to the exit door at all time, ensure that all support equipment is checked and ready to be used in case of necessity and maintain direct contact with the healthcare team;
- Reduce external stimuli;

- Ensure that the environment is privative, calm and cozy;
- Ask the participant about their preferences regarding the light intensity and room temperature. Make it clear that these parameters can be adjusted any time the subject want;
- Conduct all the assessments and data extraction points with at least two and no more than three persons in the room at the same time;
- Avoid leaving the participant alone in the room;
- Ask the volunteer to shut down their phone;
- Early assessment and resolution of participant's needs;
- Remove individuals that may destabilize the subject. If this individual is the main investigator, switch with another staff member if it is feasible;
- Maintain physical distancing from the volunteer, respecting his or her individual space. Avoid unnecessary touches;
- Provide support if the participant wants to walk or go to the bathroom, be aware of risk of falling or accidents (impaired motor coordination, intense sensory and perceptual alterations).

Staff Behavior

- Introduce yourself and other research personnel who will be in contact with the participant;
- Always be supportive and respectful with the volunteer;
- Speak slowly, softly and calmly during the assessments. Any instruction or question must be clear and objective;
- Avoid sudden, sharp movements;
- Be attentive to the participant and their needs, refrain from using a cellphone or making annotations;
- Reassure the short-lived condition of the psychoactive effects;
- Encourage the subject to experience their feelings in a free, supportive way;
- If the participant wants to express their feelings or thoughts, listen in an attentive, non-judging way. Do not confront or try to guide or provide interpretations to the experience.
- If being with the participant becomes a distressing or excessively psychologically demanding task, switch with another available staff member if it is feasible;

Severe Adverse Situations

- Prevention and early detection and intervention are the foremost decisions to achieve better outcomes; Be always aware and ready to detect and act in case of a potentially severe adverse situation as soon as possible. Do not adopt a watchful waiting stance without communicating with the rest of the team about the situation;
- Check the operational protocols: "Acute Anxiety", "Psychotic episode", "Psychomotor agitation and aggression", "Suicidality", "Alterations in Vital Signs";
- Inform the medical staff about the situation as soon as possible and follow their guidance. The healthcare professionals can overrule the research staff in case of need and they have the final word relating to health concerns;
- Any severe adverse event must be documented in the clinical research medical record;

Post-Session

- Ensure that the participant is in good condition (both physical and psychological) to safely return home;
- Ensure that the participant is in company with someone he trusts (such as a close friend or a relative). Discourage them from being alone after the experimental session;
- Encourage resting and light activities. Tell the participant to avoid intense or demanding activities and the use of recreational drugs;
- Contact the volunteer 12 and 24 hours after the end of the experimental session. Ask for their general condition, adverse effects and the eventual use of recreational or prescription drugs, focusing in addressing the participant's needs and building rapport;
- Educate the volunteer about potential adverse reactions and provide contact numbers of the research team to be contacted in case of demand;
- If some severe adverse effect is identified or reported, promptly inform the study coordinator and the psychiatrist in charge;
- Register any event or relevant information in the clinical trial medical record;
- Perform the follow-up assessments according to the study's protocol

- *Documentation* Perform a detailed recording of the experimental session, adverse reactions and management, general conditions at the end of the session and follow-up contacts;
- Further information on the recording can be found in the operational protocol "Clinical Trial Patient Record".

Observations

- Remain close to the participant and attentive to their needs throughout the experiment, including observing physiological needs and offering food and water.
- Severe adverse situations and reactions should be referred to and managed by the clinical team of the study (nurses, doctors, and psychologists) according to specific protocols.
- All management should be based on a non-directive, supportive approach, without the use of specific psychotherapeutic techniques (unless included in the study).
- Prioritize the use of this protocol for general management, emphasizing verbal and environmental management before resorting to specific adverse reaction protocols.

Responsibility

Research Staff of the Laboratory of Clinical Research With Hallucinogens and Psychedelics (LEAPS/FMRP-USP)

Register And Indexing

Clinical Trial Patient Record

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ANNEX 1: PRE-SCREENING FORM

General Data

Full Name:
Identity Number (RG/CPF):
Birth Date:
Address:
Phone Number:
E-mail:
Weight:
Emergency contact (relative or a trusted friend)
Name:
Phone Number:

Known physical pathologies (Personal and Family History)

Cardiovascular
[ ] Arterial hypertension
[ ] Arteriovenous malformations
[ ] Aortic aneurysms
[ ] Arrhythmias
[ ] Coronary Disease
[ ] Congenital Cardiac Anomalies
[ ] Prior Myocardial Infarctions
[ ] Cardiac Insufficiency
Hepatic/Renal
[ ] Hepatitis

[ ] Previous drug hepatotoxicity
[ ] Hepatic Insufficiency
[ ] Other Hepatic Diseases: _____
[ ] Acute Renal Insufficiency
[ ] Chronic Renal Insufficiency
[ ] Other Renal/Urinary diseases: _____

Neurological

[ ] Intellectual or Learning Disability
[ ] Loss of consciousness, fainting
[ ] Convulsions
[ ] Epilepsy
[ ] Migraine
[ ] Cerebrovascular Accident

Other

[ ] Diabetes mellitus
[ ] Hypo/Hyperthyroidism
[ ] Respiratory Diseases: _____
[ ] Autoimmune diseases
[ ] Allergies: _____
[ ] Past surgeries _____

Known mental Disorders (Personal and Family History)

[ ] Schizophrenia
[ ] Other psychotic disorders:_____
[ ] Bipolar Affective Disorder
[ ] Depressive Disorders: _____
[ ] Anxiety Disorders: _____
[ ] Personality Disorders: _____
[ ] Drug use Disorders: _____
[ ] Obsessive-Compulsive Disorder
[ ] ADHD
[ ] Autism Spectrum Disorders
[ ] Other _____

Past and Current medication use

[ ] Antidepressants _____
[ ] Benzodiazepines _____
[ ] Mood-Stabilizers _____
[ ] Antipsychotics _____
[ ] Anticonvulsants _____
[ ] Appetite Suppressants _____
[ ] Amphetamines _____
[ ] Herbal medications (phytotherapeutics) _____
[ ] Cannabinoids _____
[ ] Other _____

Recreational Drug Use (Try to specify the quantity and frequencies in lifetime, last year, last month)

[ ] Tobacco
[ ] Alcohol
[ ] Cannabis
[ ] Amphetamines
[ ] Cocaine
[ ] Inhalants
[ ] Opioids

[ ] Hallucinogens
[ ] Drugs used in religious contexts (i.e. ayahuasca)

OPERATIONAL PROTOCOL - MANAGEMENT OF PSYCHOMOTOR AGITATION AND AGGRESSIVE BEHAVIOR IN THE CONTEXT OF CLINICAL RESEARCH WITH HALLUCINOGENIC SUBSTANCES.

Objectives

- Ensure the safety and psychological and physical well-being of the participant using hallucinogens in the context of clinical research;
- Properly manage participants exhibiting disorganized behaviors, aggression, self-harm, harm to others and/or psychomotor agitation during the acute effects of the applied intervention.
- To standardize the care and actions of professionals involved

Field Of Application

Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto (FMRP-USP). Department of Neuroscience and Behavioral Sciences, Mental Health Program (FMRP-USP).

Materials And Procedures

It is mandatory for the staff to engage in non-restrictive approaches, which involve: organizing the physical space (environmental management); establishing a dialogue for mutual collaboration (verbal management) and adjusting the behaviors of professionals to strengthen the therapeutic relationship. If success is not achieved through these measures, it is necessary to reach the health professional in charge for situation assessment and case management. The clinical team may use pharmacological management (with oral or intramuscular drugs) to achieve control over aggressivity and agitation, if necessary. If verbal, environmental and pharmacological measures are proven insufficient, the need for physical and mechanical restrainment should be considered. Physical an mechanical restraint should only be determined by the medical professionals, via prescription (according to the respective Operational Protocol, available in Athos system). In the absence of a medical professional in an emergency situation, the nurse is supported by Federal Nursing Council Resolution 427/2012 to prescribe and initiate patient restraint. The nurse should inform the medical team and request an evaluation. Non-healthcare professionals should not determine any form of physical or mechanical restraint.

Additional Information

- Prioritize active listening to the patient, trying to address and solve their complaints;
- Never approach the patient alone. If the patient exhibits paranoid or aggressive behavior toward a specific team member, the member must be removed from the scene immediately;
- Continuously reinforce with all the team the need for implementation of measures to avoid or minimize aggressive behavior and psychomotor agitation;
- The patient must be informed all the time, allowing for the expression of feelings and understanding the situation in a supportive and non-punitive manner;
- Assisting professionals must be trained and up-to-date whenever it is possible;
- After a management process, team evaluation of the situation can be useful in preventing future incidents;
- Detailed documentation of the procedure is essential, and specific institution assessment tools should be filled out;
- It is important to note that there is a lack of consensus in the literature regarding physical and mechanical restraint measures, as well as a lack of evidence. Therefore, each case should be carefully, critically, and individually evaluated involving the entire team.

Responsibility

The Resolution 1.598/2000 of the Federal Council of Medicine stipulates that it is the responsibility of the medical professional to decide on patient restraint. The Regional Nursing Council of São Paulo, in Resolution 427/2012 of the Federal Nursing Council, states that a nurse can prescribe restraint if there is a shared protocol authorizing it, with the execution of the restraint carried out by nursing technicians and assistants under the supervision of the nurse. In general, the

scientific literature encourages all healthcare team professionals to participate in the decision-making process regarding physical/mechanical restraint, as well as any procedure, provided they are adequately trained for it. This facilitates a greater role for the interdisciplinary healthcare team, reducing the sole decision-making power of one professional and thus preventing potential abuse or inappropriate conduct towards the patient.

Registration And Indexing

"Nursing Care Record" Form in the Electronic Patient Record (PEP - Prontuário Eletrônico do Paciente)

Clinical Research Patient Record.

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OPERATIONAL PROTOCOL - MANAGEMENT OF ACUTE ANXIETY AND PANIC ATTACKS IN THE CONTEXT OF CLINICAL RESEARCH WITH HALLUCINOGENIC SUBSTANCES.

Objectives

- Ensure the safety and psychological and physical well-being of the participant using hallucinogens in the context of clinical research;
- Properly manage participants exhibiting intense psychological distress and anxiety-like symptoms during the acute effects of the applied intervention.
- To standardize the care and actions of professionals involved.

Field Of Application

Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto (FMRP-USP). Department of Neuroscience and Behavioral Sciences, Mental Health Program (FMRP-USP).

Materials And Procedures

- States of high anxiety and psychological distress are normal and expected in the context of using hallucinogenic and psychedelic substances. The entire research team should be familiar with the effects of the administered substance and the phenomenological characteristics resulting from acute substance use to differentiate between transient and self-limiting states and more severe anxiety conditions that require active management.

- Before the start of the experimental session, the patient should be informed about the possibility of experiencing anxious states and their characteristics as part of the process of obtaining Informed Consent (IC).

- Although the presence of moments of increased anxiety and psychological distress is normal and expected, their occurrence should always be communicated to the responsible healthcare professionals (doctor, nurse, psychologist) and shared with the entire research team, regardless of their role, so that everyone is prepared to action if necessary.

- The decision to either maintain supportive measures or initiate active management of the anxiety should be made by the healthcare professional overseeing the session, in collaboration with other researchers.

- Descriptions of anxious conditions and the actions taken should always be documented in the Clinical Research Patient Record.

Additional Information

In cases of identifying anxious states and psychological distress, the following actions should be taken:

- All researchers who will be accompanying a patient in psychological distress must feel calm and confident enough to do so. The professional should understand the phenomenology and dynamics of anxiety associated with the use of hallucinogenic and psychedelic substances to avoid feeling distressed or pressured to eliminate the emotional state. The researcher should act as a reassuring and respectful presence, avoiding being invasive or insistent in their approach.

- If, at any point during the session, the researcher feels that they do not have the psychological capacity at that moment to deal with the patient's psychological distress, they should inform the team and be replaced by another professional. Do not persist in managing the situation, which should always be done as a team.

- Be present the entire time. In many cases, the silent presence of a professional is sufficient for the patient to feel secure. Furthermore, it is important not to leave the patient alone to protect them from potential harm. If the patient requests to be left alone, gently inform them that your presence is necessary.

- Reassure them they are safe and being accompanied throughout the duration of the effect.

- Remind the patient that they are under the influence of a psychoactive substance and that the anxiety is due to its psychopharmacological effects and is transitory.

- Avoid having too many people present during the crisis. Ideally, the professional who will perform the management should be the one with whom the patient is most familiar and connected. The rest of the team should be on standby but not necessarily by the patient's side.

- Instruct the patient to keep their eyes open. If the patient wishes, hold their hand or lightly touch their shoulder. Never touch the patient without their consent or if they do not have the capacity to provide consent.

- In the event of management failure, worsening of anxiety, psychomotor agitation or a panic attack (feeling of imminent death or loss of mental sanity/capacity to think, restlessness, psychomotor agitation, physical symptoms such as tachycardia, chest pain, difficulty breathing), the healthcare professional present should be informed and will take full control over the management of the patient.

- The patient can be informed that if they do not improve with non-pharmacological measures or if they remain in a state of intense mental distress, medications may be used. Make it clear that this will be avoided whenever possible, but the research team will not allow the patient to remain in unbearable suffering and the patient's well-being is the main priority.

- Whenever possible, provide training and updates for assisting professionals in various anxiety management techniques (box breathing, countdown grounding, mindfulness protocols, etc.). Grounding techniques can be used at any time the researcher deems it necessary and do not pose harm or side effects to the patient if done correctly. A professional familiar with various techniques can decide which one is most suitable for a specific patient or situation.

Responsibility
Research Staff of the Laboratory of Clinical Research With Hallucinogens and Psychedelics (LEAPS/FMRP-USP)

Register And Indexing
Clinical Trial Patient Record

OPERATIONAL PROTOCOL - MANAGEMENT OF SUICIDALITY IN THE CONTEXT OF CLINICAL RESEARCH WITH HALLUCINOGENIC SUBSTANCES.

Objectives

- Ensure the safety and psychological and physical well-being of the participant using hallucinogens in the context of clinical research;

- Properly manage participants exhibiting suicidal thoughts and behaviors during the acute effects of the applied intervention and in the following days after the session.

- To standardize the care and actions of professionals involved.

Field Of Application
Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto (FMRP-USP). Department of Neuroscience and Behavioral Sciences, Mental Health Program (FMRP-USP).

Materials And Procedures

Assessment of Suicidal Risk

If the patient exhibits speech with nihilistic, despairing, or death-related content or a marked worsening of the mood or self-harming behavior is noticed, the professional should immediately initiate a suicidal risk assessment following this protocol.

- The initial assessment can be conducted by any member of the research team who has received adequate training.
- It is advisable for the assessment to be carried out by the team member who has built the best rapport with the participant.
- Ask probing questions such as: "I notice that your speech contains a lot of distress; have you ever had thoughts that it would be better to be dead?" or "Have you ever had thoughts that dying would be a possible solution?" or "Have you ever thought about doing something to hurt yourself?"
- If the patient responds affirmatively to any of these questions, inform the patient of the need for evaluation by a clinical professional.
- Immediately refer the patient for evaluation to a team member with clinical experience (nurses, psychologists or doctors).
- Do not use any religious or motivational phrases such as "This too shall pass", "Let's think positively" or "Trust in God's plans". Likewise, avoid using phrases like “This challenging experience is important and meaningful” or “Overcoming this is part of the healing the medicine provides”.
- Reinforce to the participant that they are not alone and that their concerns will be addressed by the professionals involved.
- Demonstrate being available to provide psychological support. Encourage them to talk about their feelings. Contrary to popular belief, talking about suicide does not promote the worsening of suicidal behavior.
- If in-person contact, stay close to the participant throughout the entire time in a private, calm, and welcoming environment.
- If contact is via telephone, remain in constant contact until the case is resumed by a healthcare professional.
- See ANNEX I for a Suicide Risk Assessment Interview Guide

Management of Suicidal Cases by Qualified Clinical Professionals

- The qualified clinical professional must start the proper management as soon as the suicidal risk is assessed.
- The qualified professionals are a psychiatrist, a psychologist and a nurse with training in mental health.
- Provide emotional support and verbal and environmental management.
- Identify and engage the patient's support network. Provide guidance to the family and close friends.
- After assessment, bring the discussion to the multidisciplinary team and the study coordinator.
- The course of action should be determined after discussion, on an individualized basis.
- Medication management should be carried out by a medical professional through a medical prescription and recorded in the Clinical Trial Patient Record and the Electronic Patient Record.
- Keep in close contact with the patient until the situation is finished.
- Instruct about suicide helplines (CVV: 188 [Centro de Valorização da Vida/ Life Valuation Center, the Brazilian suicide helpline]
- In the event of a suicide attempt, immediately refer to the Emergency Care Unit (UPA - 13 de Maio; UPA - Vila Virgínia; UBDS central). Notify the clinical supervisor and study coordinator immediately.

Additional Information

- In case of the identification of thoughts of death, suicidal ideation, suicidal behavior or suicide planning, the case should be assessed and managed by a clinical professional (nurses, doctors, and psychologists).
- The course of action for the case should be evaluated on an individual basis after discussion with the clinical team and project coordinators.
- Maintain direct and continuous contact with the participant until the case is resolved.
- All assessments and interventions should be documented accordingly.

Responsibility

Research Staff of the Laboratory of Clinical Research With Hallucinogens and Psychedelics (LEAPS/FMRP-USP)

Register And Indexing

- Register in Clinical Trial Patient Record and Electronic Patient Record
- Register in details all the care given and appointments made

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ANNEX 1: INTERVIEW ASSESSMENT FOR SUICIDE RISK*

Social Support

- Who do you live with? (Family, friends, alone, institution)
- Do you have children? If yes, how many? What are their ages? Describe your relationship with them.
- Do you have any personal income? If yes, please describe it. If not, how do you support yourself financially?
- Are you currently employed? If yes, what is your profession/occupation? If not, how long have you been inactive, why, and when was your last job?
- Do you have a religious affiliation? If yes, please describe it (type of religion and religious practices, frequency of attending services/masses).
- Do you engage in social or leisure activities? If yes, please describe them.

Investigation of Previous Suicide Attempts

- What method did you use in previous suicide attempts? (medications, poisons, firearms, sharp objects, hanging, jumping from heights, etc.)
- Did you communicate your suicidal intentions before the attempt? (No communication, unclear communication, clear communication)
- Did you take precautions to prevent anyone from stopping you? (No precautions, unclear precautions, clear precautions)
- Did you take precautions for someone to find you after the attempt? (No precautions, unclear precautions, clear precautions)
- Did you actively seek help after the attempt? If yes, please describe.

Current Suicide Risk

- If yes, specify if there are recurrent thoughts of death, suicidal ideation, or suicide planning.
- Do you have social support?

- Do you have access to lethal means? (Medications, poisons, firearms, living in a high place, living in an isolated area, etc.)
- Do you have any professional risk factors (healthcare professionals, police officers, others)?
- Are you open to mental health treatment?

* *Adapted from: Serviço de Manejo Integrado de Psiquiatria de Emergência do Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto da Universidade de São Paulo.*

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OPERATIONAL PROTOCOL - REGISTERING AND INDEXING INFORMATION RELATED TO THE CARE OF PARTICIPANTS IN EXPERIMENTAL SESSIONS WITH HALLUCINOGENIC SUBSTANCES IN CLINICAL RESEARCH

Objectives

The Clinical Research Patient Record (CRPR) is a set of documents containing data and notes related to the health status of research volunteers and the assistance provided to them. It is a document of fundamental importance in all research involving human subjects with any medical condition. The CRPR serves the following purposes:

- To systematically and objectively record relevant information about the volunteer and their health status before, during, and after experimental sessions, and to facilitate access to this information if necessary.
- To standardize the flow of information among research team members.
- To ensure that all measures related to the care of the volunteer in clinical research settings are appropriately taken.

Field Of Application

Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto (FMRP-USP). Department of Neuroscience and Behavioral Sciences, Mental Health Program (FMRP-USP).

Materials And Procedures

Screening and Pre-Experimental Session

- Fill out the Pre-Screening Form (see Annex I) and attach it to the Clinical Research Patient Record (CRPR).

- If a participant's profile matches the study criteria and they express a desire to participate, forward the completed Pre-Screening Form to the professional responsible for conducting the Structured Clinical Interview for DSM-V (SCID-V - clinical version).

- Conduct the Structured Clinical Interview for DSM-V (SCID-V - clinical version), either via phone or in person, and record it in the research protocol (psychologist or psychiatrist).

- Attach any relevant documents (e.g., reports and records provided to the team by the patient's attending physician) to the CRPR

Experimental Session

- Upon the participant's arrival at the location, open the Interference in Experimental Session Form (Annex II). This form should be within reach of the responsible researchers throughout the experiment and should be adequately filled out with any necessary information.

- Request the participant to complete the Informed Consent Form and attach it to the CRPR.

- In case of an incident that requires action by the research team, briefly record it in the Interference in Experimental Session Form and provide detailed information in the CRPR.

- Notes related to any incidents in the CRPR must include: a detailed description of the incident, assessment and actions taken, date, and the signature and stamp (if applicable) of the researcher responsible for the note.

Post-Experimental Session

- All contacts with the patient, including those conducted by phone, should be recorded in the CRPR, along with any provided instructions or actions taken, properly noted and signed by the responsible person.

Additional Information

- The CRPR must always be attached to the other documents of the patient when they become involved in a clinical research study.

- All other documents related to the volunteer's health status should be attached to the CRPR as described above.

- In addition to the attached documents, the CRPR consists of one or more letterhead sheets with the research institution's information, on which relevant notes are recorded as described above.

- Notes made in the CRPR:

1. Must be written in pen.

2. Must not have any erasures.

3. Should be clear and concise.

4. Must be dated.

5. Should be accompanied by the signature (and stamp, if applicable) of the researcher responsible for them.

6. Should be made sequentially, without leaving blank spaces between consecutive entries.

- The CRPR must be kept in the custody of the research team for the entire duration of the experiment.
- In case of any doubts regarding the completion of the CRPR, consult the research supervisor responsible for the study.

Responsibility
Research Staff of the Laboratory of Clinical Research With Hallucinogens and Psychedelics (LEAPS/FMRP-USP)

Register And Indexing
Clinical Trial Patient Record

ANNEX 2: INTERFERENCE IN EXPERIMENTAL SESSION FORM

Name: _____
Date: _____/_____/_____
Time of Patient's Arrival at the facility: _____h_____m

Toxicologic Screening:

Alcohol: [ ] Negative [ ] Positive
Other Drugs: [ ] Negative [ ] Positive
Pregnancy Test: [ ] Negative[ ] Positive [ ] Not applicable

Complaints at admission:
[ ] No
[ ] Yes
Describe:
_____
_____
_____
_____
_____
_____

Time of substance administration: _____h_____m.
Administered by:_____

Incidents during the experimental session:
[ ] No
[ ] Yes
Describe:

_____
_____
_____
_____
_____
_____

The patient left the research facility at _____h_____m, under the care of _____, their accompanying person.

Complaints on discharge:
[ ] No
[ ] Yes
Describe:

_____
_____
_____
_____
_____
_____

Researcher's signature _____