

# Procedures for observational research with psychedelics at the Faculty of Psychology and Neuroscience at Maastricht University

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## Aim of this document

This document describes the procedure for observational research with psychedelics at the Faculty of Psychology and Neuroscience (FPN), Maastricht University. It has been assessed and approved by the Ethics Review Committee of Psychology and Neuroscience (ERCPN) and consists of professional standards for observation research. Before conducting any observational research, the research team should obtain ethics approval from ERCPN at FPN.

You can indicate in the ERCPN-application form that you adhere to the “for observational at psychedelic retreats” procedure. If you do, then the ERCPN will generally approve this aspect of the Project. Next, you do NOT have to copy or paraphrase any text from the Procedure document in your proposal, since then ERCPN will treat it as a possible deviance from standard procedure. Research proposals can still be submitted that deviate (justified) from the Procedure, and the deviations will then be reviewed for ERCPN.

## Disclaimer

The FPN-researcher shall not advocate the use of psychedelics nor is it responsible for the organization of psychedelic retreats where it collects observational data. The red colored disclaimer in the template of the information letter is mandatory to add:

- In English: We do not promote or encourage the use of psychedelics. Therefore, the University of Maastricht cannot be held liable for possible adverse effects or inconveniences arising from the use of psychedelics on your own initiative. Because not much research has yet been done into the potentially harmful effects of psychedelics, we cannot rule out that using these substances can negatively affect you in the short or long term.
- In Dutch: Wij promoten of stimuleren het gebruik van psychedelica niet. De Universiteit Maastricht kan dan ook niet aansprakelijk worden gesteld voor mogelijke nadelige effecten of ongemakken die voorkomen uit het gebruik van psychedelica op eigen initiatief. Omdat er nog niet veel onderzoek is gedaan naar de mogelijke schadelijke effecten van psychedelica, kunnen we niet uitsluiten dat het gebruik van deze middelen u op korte of lange termijn negatief kan beïnvloeden.

### **Starting an observational study with psychedelics**

Observational research at psychedelic retreats at FPN should be conducted with the utmost care and professionalism to ensure quality research and independence from the psychedelic retreats through which data is gathered. Below is a standard operating procedure for conducting observational research at psychedelic retreats. By following this standard operating procedure, researchers can conduct observational research at psychedelic retreats in a safe, ethical, and professional manner, while contributing to the advancement of psychedelic research.

### **Research team**

The research team should contain senior researchers who are experienced in observational research at psychedelic retreats, and who can offer guidance and supervision to junior researchers (PhD/post-doc) and student interns. Senior researchers include all authors of the present procedure. Student interns will always be accompanied by a junior or senior researcher when visiting psychedelic retreats for observational research. Student interns will always sign an intern contract with FPN to ensure that they are aware of FPN's rules and agreements.

### **Independence**

FPN will not interfere with or give advice on practical operations at psychedelic retreats as the role of FPN at such retreats will only be 'observational'. Data collected as part of observational research at psychedelic retreats will be owned by FPN. Psychedelic retreats will not be invited as scientific collaborators of 'observational' research' in order to avoid conflicts of interest. As a rule, psychedelic retreats are responsible for all activities within the retreats that are "under observation" by FPN researchers. FPN researchers are solely responsible for their observational research.

### **Site selection**

It is not always possible to evaluate the credentials of psychedelic retreats (i.e. individuals or centers that offer facilities for a psychedelic experience) with whom we would like to collaborate. It is clear however that standard operating procedures of retreats do not meet standard operating procedures for clinical trials with psychedelics in academic or clinical settings. Many psychedelic retreats are driven by spiritual and commercial interests and generally are less focused on medical interests. In general, this is fine from an observational point of view, as long as it is clear that retreats are not imposing 'unethical' procedures on their clients. For example, sites that use

'waterboarding' or 'tasers' to 'ground' participants of psychedelic retreats must be avoided and placed on a 'black list' of retreats with whom FPN will not collaborate. Other examples could include retreats that experiment with dangerous cocktails of psychedelics (5-MeO-DMT as a dessert to ayahuasca) or administer potentially life-threatening psychedelics (such as ibogaine) without proper medical controls. Senior researchers will evaluate the standard operating procedures of psychedelic retreats before any collaboration. Psychedelic retreats with whom we have successfully collaborated in the past are placed on a "white list". This list can be expanded with novel retreats upon evaluation of their operating procedures.

### **Blacklist of psychedelic retreats**

The blacklist will be constructed by and shared among psychedelic researchers at FPN and evaluated and updated on a regular basis (e.g. following each novel evaluation of a psychedelic retreat). For example during their regular psychedelic research meetings. In ERCPN applications, researchers will indicate, if possible, why they believe that a collaborating retreat is trustworthy (e.g. already present on the white list or because an organization has not been associated with malpractice). Psychedelic retreats will be placed on the black list in case of evidence of malpractice (as defined in the list of malpractices).

### **Legal vs illegal psychedelic retreats**

Most psychedelic retreats are illegal as they sell and provide experiences with scheduled drugs. There are 'legal' exceptions such as retreats in the Netherlands that offer non-scheduled mushrooms that contain spores of psilocybin (truffles). The legal status of a psychedelic retreat however is not relevant for site selection because FPN researchers are not a responsible party in the organization of retreats.

### **Participant recruitment**

Participants in observational research should be recruited through informed consent, and they should be fully informed about the nature of the research, the potential risks and benefits, and their right to withdraw from the study at any time. Participants should be made aware that the UM researchers are not in charge or responsible for any of the activities and procedures within the psychedelics retreat, apart from the research in which they participate. Independence of FPN from the retreat activities will be explicitly stated in the informed consent that participants will sign.

### **Responsibility of FPN researchers at psychedelics retreats**

The sole responsibility of FPN researchers who are present in person at an observational site, is the quality and logistics of their research. In the event of a medical emergency among retreat participants, the hosting retreats should take action and organize medical help. If this fails, every individual present at the retreat, including FPN researchers, should follow common societal rules and responsibilities and call a medical emergency team.

### **Promotional activities of psychedelic retreats**

Observational research at psychedelic retreats can only take place in the absence of any promotion of the research at a psychedelic retreat. Visitors of psychedelic retreats should not be motivated to join a retreat because they wish to participate in observational research of FPN. Therefore, visitors of psychedelic retreats should only become aware of FPN research, after they signed up for a retreat. On their websites, psychedelic retreats can refer to publications of FPN

that are based on observational research in their centers, provided that the retreat was also acknowledged in the publication.

### **Observation**

During the retreat, the research team can use objective and subjective measures of participant behavior, emotional state, and any adverse reactions. The team should also collect data on the dosage, timing, and mode of administration of the psychedelic substance.

### **Data analysis**

The data collected during the retreat should be analyzed using appropriate statistical methods to determine the effects of the psychedelic substance on the participants' behavior, emotions, and mental state.

### **Reporting**

The findings of the observational research should be reported in a professional and ethical manner, taking care to protect the confidentiality and privacy of the participants.

### **Contacts**

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