Ethical Limbo and Enhanced Informed Consent in Psychedelic-Assisted Therapy
– Identifying New Challenges and Ethical Dimensions

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“If knew that either of my daughters would eventually develop a fondness for methamphetamine or heroin, I might never sleep again. But if they don’t try a psychedelic like psilocybin or LSD at least once in their adult lives, I will wonder whether they had missed one of the most important rites of passage a human being can experience.”

Sam Harris, Waking Up: Searching for Spirituality Without Religion (Harris, 2014, p.189)

“Was it possible that a single psychedelic experience—something that turned on nothing more than the ingestion of a pill or square of blotter paper—could put a big dent in such a worldview? Shift how one thought about mortality? Actually change one’s mind in enduring ways? The idea took hold of me. It was a little like being shown a door in a familiar room—the room of your own mind—that you had somehow never noticed before and being told by people you trusted (scientists!) that a whole other way of thinking—of being!—lay waiting on the other side. All you had to do was turn the knob and enter. Who wouldn’t be curious?”

Michael Pollan, How to Change Your Mind (Pollan, 2019, p.15)
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Abstract

Human cultures have used classic psychedelics for healing purposes for millennia, emphasizing their subjective effects. In the 21st century, research has been revived to investigate the therapeutic effects of these substances. These substances show promising results in the treatment of various mental-related disorders such as depression, post-traumatic stress disorder, and others, necessitating ethical considerations and guidelines for researchers, psychotherapists, and policymakers. The subjective effects of the psychedelic experience that these substances evoke, such as the feeling of oneness and interconnectedness, infallibility, the sense of reduced one’s self-importance, the encounter with the “ultimate” reality or with God, radically distinguish them from typical psychiatric medications such as selective serotonin reuptake inhibitors (SSRIs). In their essay “Ethics and Ego Dissolution: the Case of Psilocybin”, William R. Smith and Dominic Sisti argue that the special properties of psychedelics entail certain novel risks that warrant “enhanced” informed consent that is “one that is more comprehensive than what may be typical for other psychiatric medications” They emphasize the unique effects of these substances, including 1) the potential for significant personality changes, 2) the short duration of treatment, and 3) the potential for profound and transformative experiences. They highlight the importance of explicitly addressing these potential changes as part of the informed consent process to ensure patient understanding, autonomy, and well-being. This current paper substantially complements Smith and Sisti’s work by discussing in more detail the differences between psychedelics and typical psychiatric medications with respect to informed consent. I first support their arguments and then further argue that there are three other critical reasons why psychedelics should not be treated like other psychiatric medications that should be considered when discussing the enhancement of informed consent and disclosure. 1) potential changes in ethical values, 2) Set and setting, and 3) suggestibility. To clarify my argument, I propose a distinction between changes in worldview and ethical values induced by the psychedelic experience and emphasize their differential impact on individuals undergoing psychedelic therapy. I introduce the term “ethical limbo”, characterized as a state of uncertainty or ambiguity regarding the ethical implications or consequences of a particular action, decision, or situation due to conflicting ethical values, to highlight a potential risk of the psychedelic experience that should be considered in informed consent. Finally, I address potential objections to my arguments before concluding the paper and addressing some limitations of the research.

Keywords: classic psychedelics, psychedelic experience, mystical experience, biomedical ethics, informed consent.
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1. Introduction

Human cultures have used hallucinogenic plants in ceremonial settings for spiritual, recreational, and therapeutic purposes for thousands of years (Nichols, 2016; Santos et al., 2011; Strassman, 1984), if not as far back as the Bronze Age (Guerra Doce et al., 2023) and even earlier (Schultes, 1969). Recent evidence indicates that public use of these substances has increased over the past decade in the United States and other countries for recreational purposes (Sexton et al., 2019), religious purposes (Hartogsohn, 2021), and personal growth (Hadar et al., 2022). Psychiatrist Humphry Osmond first used the term "psychedelics" to refer to this class of hallucinogenic plants in the 1950s. The term is composed of the ancient Greek words psychē (ψυχή, "soul") and dēloun (δήλον), "to make apparent or manifest", meaning "to manifest the mind" (Osmond, 1957). In general terms, "psychedelics" are psychoactive substances and a subclass of hallucinogenic drugs that have a profound impact on perception, emotions, sense of self, personality, belief systems, and interpersonal relationships by acting primarily as agonists at the serotonin-2a (5-HT2a) receptor in the brain (Kettner et al., 2019; MacLean et al., 2011; Nichols, 2016; Swanson, 2018). The phrase "psychedelic renaissance" is now used by academics and the general public to describe the revival of academic interest in psychedelic research over the past decade (George et al., 2019; Kohli, 2013; Pollan, 2019). Around 500 psychedelic studies are now being conducted by the US National Institute of Mental Health, one of the largest research medical financiers in the world (http://clinicaltrials.gov). Ingestion of psychedelic substances generally appears to be physically harmless (Gorman et al., 2021), but has unique psychological effects that radically distinguish them from typical psychotropic drugs such as selective serotonin reuptake inhibitors (SSRIs) and thus, require special ethical discussion.

The ingestion of psychedelics causes a temporarily altered state of consciousness lasting between 5-8 hours marked by intense feelings ranging from terror to awe-inspiring experiences, which can cause a rapid change of worldview that would otherwise occur only haphazardly (Davis et al., 2020; Griffiths et al., 2008; Grof, 1976; Móró et al., 2011). Several hypotheses and theories have been developed to explain the psychedelic experience. Some of these draw on pre-existing theories of consciousness, such as Gerald Edelman and Giulio Tononi’s theory "Integrated Information Theory" (Tononi, 2004; Tononi & Edelman, 1998), while others draw on the neural correlates and psychoanalytic terminology, such as the "Entropic brain hypotheses" developed by Robin Carhart-Harris and colleagues (Carhart-Harris & Friston, 2019; for review, see Swanson, 2018).
Philosopher Peter Sjöstedt-Hughes provided in 2016 a chronological overview of the history of major Western philosophers from Plato (c. 427-347) to Michel Foucault (1926-1984) who have been involved with psychoactive substances and how this may have influenced their thinking and ultimately Western philosophy as a whole (Sjöstedt-H, 2016). Philosophers such as Aldous Huxley and Huston Smith explicitly investigated and commented on the effects of psychedelics in the twentieth century (Huxley, 1954; Smith, 1964). However, it was not until the second decade of the twenty-first century that psychedelics began to receive significant attention in academic philosophy and ethics (for an overview of some of the philosophical debates, see Letheby & Mattu, 2022). While psychedelic psychiatry has recently experienced a renaissance and could be of significant benefit to patients with severe mental disorders, Brian D. Earp has discussed the ethics of using psychedelics as moral enhancement in an essay arguing that biomedical ethicists have not paid sufficient attention to the potential of these substances, which is hard to disagree with (Earp, 2018). In this paper, I aim to fill that gap, or at least a small part of it.

1.1 The Aim

In short, since the 1960s, belief in and discourse about psychedelics have changed considerably, in the Global North. In the late Cold War era, psychedelics were increasingly associated with CIA experimentation, concerns about "mind control", and prohibitive public health discourse that emphasized the risks of negative mental health consequences, after initially being associated with freedom and flourishing in the 1960s as a result of "free love" movement (Hartogsohn, 2022; Lee & Shlain, 1992). After being banned for more than 50 years, the study of psychedelics is now making a comeback in psychiatric research. And widespread clinical use of these substances will probably follow, necessitating ethical consideration and guidelines for researchers, psychotherapists, and policy makers. To this end, this paper addresses the question “What information should the patient should be aware of prior to psychedelic therapy as part of the informed consent process?” Smith and Sisti (2020) addresses this topic in their paper “Ethics and ego dissolution: the case of psilocybin” by asking the question "Under what circumstances is it morally acceptable to administer such an unusual and potentially transformative intervention, induced by psychedelics in research and clinical settings?”.

In their paper, Smith and Sisti argue that the special properties of psychedelics, which distinguish them from Selective serotonin reuptake inhibitors (SSRIs) and
antipsychotics, carry certain novel risks that warrant "enhanced" informed consent clarified as "one that is more comprehensive than what may be typical for other psychiatric medications" (Smith & Sisti, 2020, p.807). They cite three critical reasons why psychedelics should not be treated like other psychiatric medications in terms of informed consent. 1) although the results are still preliminary, the personality changes induced by psychedelics differ in both type and magnitude from those produced by conventional psychiatric interventions as measured by the Five-Factor Model of personality (for a review of the model, see McCrae & John, 1992). There is evidence that psychedelic substances cause an increase to trait extraversion (a trait corresponding to sociability) and trait openness to experience (a trait corresponding to intellectual curiosity and willingness to try new things) significantly more than typical psychiatric pharmaceutical interventions. In other words, participants become more social, intellectually curious, and willing to try new experiences. 2) the course of treatment lasts much longer with typical psychopharmacological interventions than with the use of psychedelics. In the former case, participants who have already gone through part of the therapeutic process can use their experiences to make informed decisions about whether or not to continue the process. In contrast, in psychedelic interventions, patients may not have the same luxury of time to reflect and make decisions. It is well known that the effects of psychedelics occur relatively quickly, with single doses in a session that lasts for approximately 8 hours, which may limit patients’ ability to thoroughly consider the potential implications of the treatment. 3) other than the personality changes, unlike conventional antidepressants, psychedelics can produce altered states of consciousness that participants describe as profound, ineffable, and that they have deep connections between all things, an encounter with ultimate truth, reality, which lead to a change of their world view which necessitates an enhancement of the informed consent.

The present paper substantially complements the work of Smith and Sisti by providing a more detailed discussion of the differences between psychedelics and typical psychiatric medications with respect to informed consent. I will first support their arguments and then further argue that there are three other critical reasons (one of which is an extension of Smith and Sisti’s first reason, “the personality changes”) why psychedelics should not be treated like other psychiatric medications that should be considered when discussing the enhancement of the informed consent and the disclosure of information. 1) The change in ethical values: I distinguish here between changes in worldview and changes in ethical values in terms of “personality changes” caused by the psychedelic experience. Although the two are interrelated, I will show that such a distinction is necessary in educating the patient about the
therapeutic process and its long-term implications. 2) Set and setting: here I first show how the patient’s mind set, the setting (environment) in which the therapeutic session takes place, and the cultural context have a major impact on the outcome of the therapeutic process, and I argue the importance of disclosing the patient about this information. 3) Suggestibility: there is strong evidence that psychedelic substances induce a state of suggestibility, i.e., an increased tendency to accept and act on the ideas or attitudes of others, and openness to new experiences and ideas during and after the intoxication. I argue that patients in such a state are very susceptible to influence and may jeopardize their autonomy, of which they must be aware before undergoing therapy. To be more precise, I will argue that the administration of such transformative experiences could lead to a profound shift in worldview and, accordingly, a potential shift in the patient’s ethical values and, consequently, to what I refer to in the paper as "Ethical Limbo", briefly defined as "a state of uncertainty or ambiguity regarding the ethical implications or consequences of a particular action, decision, or situation due to conflicting ethical values". Furthermore, I’ll demonstrate how the set and setting, and suggestibility features of psychedelic-assisted therapy are distinct from those of conventional psychotherapy combined with conventional psychiatric medications which necessitate informing the patients about them. Finally, I will address possible objections before concluding with some suggestions for future research that might support psychedelic-assisted psychotherapy to mitigate the risks of "Ethical limbo".

The structure of the paper is as follows. In Section 2, I provide an overview of the main concepts used in this paper, an overview of the relevant evidence for the therapeutic and subjective effects of psychedelics, and what psychedelic-assisted therapy looks like. In Section 3, I focus primarily on informed consent, reiterating and supporting the arguments and suggestions of Smith and Sisiti. I then provide three more reasons why psychedelics should not be treated like typical psychotropic drugs in terms of informed consent. In Section 4, I address and respond to several possible objections to my arguments.
2. Background

2.1 Psychedelic and Personality

There are two definitions and clarification of terminology must be made before proceeding. The first is "Psychedelics" and the second is "Personality". The use of the term "psychedelic" seems to be a subject of constant debate. Some limit it to serotonergic or "classical/or classic" psychedelics, which are considered to have identical effects on the brain (Murnane, 2018; Nichols et al., 2017). To date, the best-known and most researched "classic psychedelics" include psilocybin from the fungus Psilocybe (the psychoactive component of the so-called magic mushrooms), mescaline from cacti such as peyote (the psychoactive ingredient in the plant Lophophora williamsii), lysergic acid diethylamide (LSD), and N, N-dimethyltryptamine (DMT), the primary psychoactive component of the plant Psychotria viridis, as well as ayahuasca (also known as hoasca or yage, a brown beverage used by Native Americans that is produced by fermenting the two plants Psychotria viridis, containing DMT, and Banisteriopsis caapi, which contains tetrahydroharmine and other chemicals that act as inhibitors of monoamine oxidase (MAOI) and degrade DMT, allowing its oral ingestion and leading to longer-lasting effects) (Mckenna et al., 1984; Murnane, 2018; Nichols, 2016).

Others, however, would define the term "psychedelic" more broadly to include all substances with "mind-manifesting" effects such as the 3,4-methylenedioxymethamphetamine (MDMA) commonly known as ecstasy and molly, which has a different mechanism of action in the brain and phenomenological effect than the "classic psychedelic" (Mechan et al., 2002).

The first understanding of the term "psychedelics", namely "classic psychedelics", is used in this paper for a reason that is essential and relevant to the core of this paper, namely because it has been shown that "classical psychedelics", unlike other psychedelics such as MDMA, are capable of including altered states of consciousness usually interpreted by the participants as spiritual and is referred to in the scientific literature as a "mystical experience". Even though the clinical use of MDMA in a controlled clinical setting has similar therapeutic effects to psilocybin, LSD, and others, they have different neurological and phenomenological effects than classical psychedelics. Although Smith and Sisti’s (2020) paper focuses primarily on psilocybin (a classical psychedelic), perhaps because psilocybin is currently undergoing a phase 2 trial (Carhart-Harris et al., 2021) and is expected to be approved as a drug by the Food and Drug Administration (FDA), I will include all classical psychedelics in my paper. The reason is that they all have similar neural correlates, phenomenological and therapeutic effects, as I will show in the next section. Therefore, they can be expected to undergo clinical
trials and possibly be approved by the FDA in the near future. Moreover, the ethical implications of using these substances in therapeutic settings are similar.

The term "Personality" is central to this paper but it is somewhat ambiguous or elusive when it comes to classic psychedelics since these substances can have profound effects on a person’s traits, self-narrative, and worldview. Some argue that personality changes can be attributed to the therapeutic and neurological effects of psychedelics (Letheby, 2015), while others rely on empirical studies to attribute therapeutic effects and personality changes to the subjective effects of psychedelics (Yaden & Griffiths, 2021). Either way, it seems to me that both aspects must be kept in mind when considering the ethical implications of the therapeutic use of psychedelics. When discussing psychedelics, the patient’s traits, values, beliefs, worldviews, and self-narrative are essential to the discussion. Smith and Sisti use a broad definition of personality that I share in this paper, namely "the narrative features and values of an agent that make them a distinctive (type of) person" (Smith & Sisti, 2020, p.808). According to this definition, personality includes a person’s "narrative features" and values. The notion of "narrative features" suggests that personality encompasses the story or narrative that an individual constructs about themselves, which encompasses their life experiences, personal history, aspirations, and self-perception. These narrative elements determine how individuals understand themselves and their place in the world. In addition, this broad definition of personality also includes a person’s values, held by an individual, which represent their core principles, moral beliefs, and guiding principles. In light of this definition, two aspects of personality must be kept in mind, one that refers to a person’s traits and the other that refers to their self-narrative including their worldview and moral values.

2.2 The Therapeutic Effects and Neurobiology of Classical Psychedelics

Recent studies have shown that psychedelics have the potential to provide lasting reductions in symptoms of various mental disorders such as depression, substance use disorders, post-traumatic stress disorder, and others (Goldberg et al., 2020; Johnson et al., 2019; Luoma et al., 2020; Wheeler & Trent, 2020). On top of that, it has been demonstrated that psychedelics are capable of considerably lowering symptoms of depression and anxiety in life-threatening cancer patients (Griffiths et al., 2016), increasing prosocial behavior, invoking a feeling of nature connectedness, increasing well-being and overall sense of morality in healthy subjects, (Earp, 2018; Forstmann et al., 2023; Gandy, 2019). There is now ongoing clinical research
that aims to replicate some of these findings (https://clinicaltrials.gov/ct2/show/NCT04630964).

As mentioned before, studies have shown that these substances can induce long-lasting changes in self-perception, and personality in addition to therapeutic effects. There is growing evidence that these effects are associated with structural and functional changes in the brain, particularly through neuroplasticity and neurogenesis (Vollenweider & Kometer, 2010). Classic psychedelics have been shown to promote neuroplasticity (the ability of neuronal networks in the brain to change through reorganization) by modulating key neurotransmitter systems, including serotonin and glutamate (Vollenweider & Kometer, 2010). These substances enhance synaptic plasticity by activating 5-HT2A receptors and promoting the release of brain-derived neurotrophic factor (BDNF). BDNF is a secreted protein that regulates many aspects of neuronal development and function in the nervous system. It is considered critical for neuronal growth and survival and plays an important role in synaptic plasticity. Studies using animal models and human neuroimaging techniques have shown that psychedelics can increase BDNF levels, which could contribute to the observed neuroplastic changes and accordingly give some explanation for the personality changes (Ly et al., 2018; Nichols, 2016; Vargas et al., 2023).

In addition to neuroplasticity, classic psychedelics have also been shown to stimulate neurogenesis, ”the process of generating new neurons in the brain”. Animal studies using psychedelics such as psilocybin (the psychoactive component of the so-called magic mushrooms) and N, N-dimethyltryptamine (DMT) have shown an increase in neurogenesis in specific brain regions, including the hippocampus. The hippocampus is critical for learning, memory, and emotional regulation, and impaired neurogenesis in this region has been linked to some psychiatric disorders (Catlow et al., 2013). Even though the precise molecular mechanisms by which classical psychedelics induce neuroplasticity and neurogenesis are still being elucidated, the ability of classical psychedelics to promote neurogenesis suggests a possible mechanism underlying their therapeutic effects and personality changes (Catlow et al., 2013).

2.3 The Subjective Effect of the Psychedelic Experience and Why is the Term Mystical Experience Used?

For millennia, indigenous peoples have used naturally occurring psychedelics for religious, healing, and ritual purposes, emphasizing their subjective effects (La Barre, 1960). As for contemporary science, scales such as the 30-item Mystical Experiences Questionnaire
MEQ30 used as a self-report scale, first developed by psychiatrist Walter Pahnke (Pahnke, 1963) and later further developed by psychiatrist and neuroscientist Roland R. Griffiths (Griffiths et al., 2006) to assess the subjective effects of psychedelic experiences in clinical trials, hence the name "Mystical Experience". The term "Mystēria" comes from the Greek root myō, meaning "to close" (the eyes), we get mýs-tēs, meaning an "initiate/initiation" into secret rites (Graf, 2017). This refers to the mystery sects of ancient Greece, such as the "Eleusinian Mysteries" in which it was speculated that participants used psychoactive plants (Kerényi, 1967; Pittaway, 2018). The MEQ30 scale consists of 30 items divided into four major subscales: 1) a sense of unity or connectedness accompanied by a sense of ego loss and feelings of sacredness, 2) experiencing positive emotions such as feelings of euphoria, peace, and love, 3) transcendence of time and space, and 4) ineffability, i.e., a feeling of difficulty to put the experience into words. It has been established in several clinical studies that the therapeutic effects of psychedelics administered in a supportive environment are related to their ability to induce these types of psychedelic experiences (Lutkajtis, 2021; McCulloch et al., 2022; Roseman et al., 2018; Yaden & Griffiths, 2021). Participants in several studies reported an encounter with an "ultimate reality, autonomous entities or beings or God" (Davis et al., 2020, p.1009), ranking it as one of the most meaningful experiences of their entire lives and sometimes comparable to the birth of a firstborn child (Griffiths et al., 2016). To put it in the words of a volunteer who received a dose of psilocybin in a study conducted at Johns Hopkins university:

"In my mind’s eye, I felt myself instinctively taking on the posture of prayer in my head. I was on my knees, hands clasped in front of me and I bowed to this force. I wasn’t scared or threatened in any way. It was more about reverence. I was showing my respect. I was humbled and honored to be in this presence. This presence was a feeling, not something I saw or heard. I only felt it, but it felt more real than any reality I have experienced. And it was a familiar place too. One I had felt before. It was when I surrendered to this, that I felt like I let go. I was gone...or I should say this earthly part of me was. It was still on the couch in some sort of suspended animation awaiting my return. I was in the void. This void had a strange and indescribable quality to it in that there was nothing to it but this feeling of unconditional and undying Love. It felt like my soul was basking in the feeling of this space. I have no idea how long this lasted. Time and space did..."
The likelihood of inducing the "mystical experience" by the use of psychedelics has not been precisely determined, but it appears that the majority of participants in the double-blind clinical trials have this kind of experience, in which the therapeutic effects and attribution of personal meaning and spiritual significance persist for at least 14 months after the experience (Barrett & Griffiths, 2017; Griffiths et al., 2008). Moreover, the induction of the "mystical experience" seems to be dose and "set and setting" dependent. This means that a sufficiently high dose of a potent psychedelic substance, together with the right state of mind, environment, and circumstances, are causal factors in the induction of the "mystical experience". In a sense, then, psychedelic therapy can be said to be an act of inducing mystical or, perhaps more accurately, transformative altered states of consciousness.

In terms of neuroscience, an explanation for the neural correlates of these experiences is usually attributed to the functional connectivity of metacognitive centers in the brain which is referred to by the term "Default Mode Network (DMN)". The DMN refers to a large-scale brain network consisting of five brain regions that are more active when people are thinking about themselves, thinking about others, engaging in self-referential processes such as thinking about the past or projecting their sense of self into the future, and daydreaming, and are less active when people are engaged in specific goal-directed tasks or activities (Raichle et al., 2001). Increased DMN activity has been observed in individuals with chronic pain, post-traumatic stress disorder, social phobia, schizophrenia, and depression (Akiki et al., 2018; Garrity et al., 2007; Gentili et al., 2009; Sheline et al., 2009). There is evidence that these regions are located near 5HT2A receptor sites, which are considered cellular targets of classic psychedelics that cause a decrease in activity in these regions (Barrett & Griffiths, 2017). This correlation could contribute to the understanding of why using psychedelic drugs causes the DMN to become less active, resulting in phenomena like "ego dissolution" and a "sense of unity" (Carhart-Harris et al., 2021).

These resulting extraordinary experiences may be interpreted by the participants as deeply meaningful religious revelations and spiritual awakenings. Some participant report being "felt reborn in a way" (Belser et al., 2017, p.376), a feeling of transcendence beyond death, a greater understanding of global connectedness, an encounter with "God" and in some cases, participants, even those without a spiritual or religious background, report having these
feelings during treatment (Gasser et al., 2014). Thus, it should come as no surprise that substances of this type have been used as sacraments in both traditional and contemporary religious and spiritual practices (Baker, 2005; Goulart, 2008; Guzmán, 2008; Hartogsohn, 2021).

Before concluding this part, it should be mentioned that some researchers have expressed concerns about the use of the term “mystical experience” because the use of such terminology could hinder scientific progress and even perpetuate misunderstanding and stigmatization (Sanders & Zijlmans, 2021). Others have questioned the epistemological integrity of such states and the ethical implications of basing a psychotherapeutic module on these substances (Letheby, 2016); still, others have argued that the epistemological status of these states is relatively unimportant from an ethical point of view compared to their ability to help people live good flourishing lives (Flanagan & Graham, 2017).

In summary, the potential of these chemicals to induce profoundly altered states of consciousness leads to an important ethical consideration regarding informed consent, especially when personality changes are involved that may lead to changes in worldviews, and, accordingly, ethical values.

2.4 What Does Psychedelic Assisted Therapy Look Like?

As mentioned earlier, indigenous cultures have used and continue to use “classic psychedelics” for a variety of purposes for thousands of years. These include healing physical and mental illness, spiritual purposes, connecting with nature, and engaging with society, culture, and family networks. Broadly, the mind, body, community, spirit, nature, daily life, spirituality, and medicine (the psychedelic substance) tend to be viewed as an integrated whole in these cultures. The imbalance or the separation between these elements is often considered the cause of illness (Labate & Cavnar, 2014; Sue et al., 2022). It is worth noting that such practices are not unusual for the Global North. Michael A. Rinella describes similar practices and beliefs in ancient Athens in his book “Pharmakon: Plato, Drug Culture, and Identity in Ancient Athens” (Rinella, 2010).

As for modern science regarding the clinical investigation of the therapeutic effects of psychedelics, the history dates back to the early 1950s, especially after chemist Albert Hofmann accidentally synthesized LSD in his laboratory (Garcia-Romeu & Richards, 2018). In the late 1970s, under the administration of former U.S. President Richard Nixon, the “war on drugs” was declared, and clinical research on psychedelics was prohibited by the UN.
During these two decades, there were many attempts to develop psychedelic-assisted therapy procedures and modules. Some of them drew on psychoanalytic theories and used low doses of psychedelics to facilitate pre-existing psychoanalytic types of therapy. Others drew on the principles and theories of transpersonal psychology and used relatively high doses of psychedelics (Garcia-Romeu & Richards, 2018). In these clinical trials, there was generally good evidence and a consensus among scholars for the safety and therapeutic potential of psychedelics in the treatment of conditions such as alcoholism and anxiety at the end of life. However, overall results were inconclusive because of methodological inconsistencies and a lack of appropriate controls, and statistical analysis, as well as the lack of use of validated assessments by contemporary scientific standards (for review, see Rucker et al., 2017).

In the 1990s, a revival of research has started. Permission was granted for some research that examined the potential of DMT, mescaline, and psilocybin and their effects on healthy subjects (Gouzoulis-Mayfrank et al., 1998; Hermle et al., 1992; Strassman, 1991, 1992, 1995; Strassman & Qualls, 1994). Over time, the therapeutic effects of psychedelics began to gain prominence, and in the 21st century, studies were conducted examining the effects of these substances on disorders such as obsessive-compulsive disorder (Moreno et al., 2006) and the treatment of anxiety and existential fear in patients diagnosed with life-threatening cancer (Grob et al., 2011) and others. Most of these clinical trials involved the administration of low to moderate doses of psychedelics with a short intervention duration of 1-3 months, in some cases supported by therapeutic models such as cognitive behavioral therapy and enhancement therapy and others (Bogenschutz & Johnson, 2016; Johnson et al., 2014; Ross et al., 2016). It should be noted that although psychedelic-assisted therapy is still in its infancy and has not yet been established, some modules are currently being used in research settings (Luoma et al., 2020). Psychedelic-assisted therapy is precisely defined by psychologist Ingmar Gorman as “A psychotherapy consisting of the administration of a psychedelic in the context of a psychotherapeutic environment and relationship, with the therapist providing psychological support and, in some cases, a specific intervention designed to align with the psychedelic experience and promote change in the target diagnosis” (Gorman et al., 2021, p.3). The process of the therapy consists of three main phases. In the first phase, which is referred to as the preparatory phase, where suitability, risk assessment, and screening procedures are assessed and an alliance between the participant and the therapists (often two, of different sexes) is established. In the second phase, let’s call it, the administration phase (sometimes more than one session), the substance is administered and monitored by the same
therapists. The third and final phase, commonly referred to as "integration", often begins one to two days after the drug session with a follow-up meeting between the patient and therapist(s) to reflect on the patient’s experience and reflect on the content of the session(s). These integrative sessions can occur once a week and sometimes last several months (Garcia-Romeu & Richards, 2018; Gorman et al., 2021). But is there an overarching consensus on what the "integration" process entails in definition and practice?

The short answer is: No. This is a relatively new practice. Over the years, many definitions and ecologies of practices have been developed to address this phase. Some of these modules are based on indigenous worldviews and practices (Coder, 2017), others on transpersonal psychology (Ortigo, 2021), still others on Jungian psychology (Cohen, 2017), others on harm reduction (Gorman et al., 2021) and others. These modules use a variety of integrative practices, to name a few: Mindfulness practices, breathing techniques, nature walks, talk therapy, self-reflection, reinforcement of new habits, shadow work, and on and on (for review see, Bathje et al., 2022). It is not possible to explore each module here, but to my knowledge, none of these modules involve a supportive ethical framework that helps aid the participants to navigate ethical questions about life-based on the new insights gained via the psychedelic experiences whether they obtain a "mystical experience” or not. This lack of consensus [which can probably be explained by the fragmentation and lack of unity among institutionalized schools of psychology and the lack of ethical support to the patients (Yanchar & Slife, 1997)] seems to have led, and will likely continue to lead, to confusion about what “integration” is and what integrative modules should be used.
3. The Informed Consent and Reasons for Enhancement

In the early days of concern for research participants, the use of informed consent was usually justified on the basis of harm reduction. Since the mid-1970s, however, protection of autonomous choice has been the primary justification for informed consent. However, stating that the protection of autonomy serves as the primary justification for informed consent requirements does not mean that this is the only function of informed consent. Neal Dickert and colleagues Dickert et al. (2017) acknowledge the importance of autonomous choice when it comes to informed consent. However, they argue that consent processes are multidimensional and limiting informed consent to autonomy may obscure the view of other important functions, namely: 1) creating transparency, 2) enabling control and authorization, 3) promoting concordance with participants’ values, 4) protecting and promoting welfare interests, 5) promoting trust, 6) meeting legal requirements, and 7) promoting integrity in research. Although there is disagreement among ethicists regarding the exact definition and components of informed consent, some contend that the term informed consent and “mutual decision-making” are interchangeable when used to describe shared decision-making between a patient and a healthcare provider (Katz, 1984), while others contend that the informed consent should be used to describe the “individual’s autonomous authorization” of a medical intervention and “conformity to social” and “legal norms” (Beauchamp & Childress, 2019).

There is an overall consensus among ethicists and legal scholars that health care professionals are required to provide their patients with all the information they reasonably expect to know about a given treatment (Berg et al., 2001). To better clarify, informed consent is ultimately comprised of basic elements that provide information to the patient regarding the process of the treatment and what it might involve, risks and potential benefits of treatment, as well as any alternative treatments that may be available (Beauchamp & Childress, 2019).

Before addressing Smith and Sisti’s arguments, I will provide an overview of what current informed consent for psychedelic-assisted treatments looks like. Generally speaking, the informed consent used in psychotherapy combined with a typical psychotropic drug is being used in psychedelic research. Johnson et al. (2008) published a paper establishing guidelines for the safety of psychedelic research aimed at minimizing potential adverse effects while supporting the safe administration of high doses of hallucinogens to human volunteers. Regarding informed consent, they point out that psychedelic experiences may be difficult to process for participants who have no prior experience with psychedelic substances. They therefore emphasize that more time is needed to discuss the effects of the psychedelic
experience than is the case with most psychiatric interventions, which can be completed in a few minutes, with the therapist explaining the side effects of treatment, such as, in the case of SSRIs and second-generation antipsychotics, gastrointestinal distress, sexual difficulties, and weight gain. After introducing these components, the clinician can invite questions and direct patients to informational materials if they find it useful. Johnson et al. (2008) provides a well-informed detail about the currently known side effects of psilocibin in which the participant must be aware of before going through the therapy. They highlight the physiological presentation by pointing out that while hallucinogens are not considered addictive and are relatively harmless physically and have a low physiological toxicity profile, some physiological symptoms may occur during the effects of hallucinogens, such as altered skin sensitivity, heat, and cold sensations, dizziness, blurred vision, dilated pupils, and a moderately elevated pulse. In addition, they point out the currently known acute psychological distress and dangerous reactions that may occur in some patients while taking hallucinogens, which should be brought up in the consent forms. They place an emphasis on what is referred to in the literature as a “bad trip”, a psychological state characterized by anxiety, panic, paranoia, and dysphoria. Such states can potentially lead to dangerous behaviors that result in aggression toward self or others. Another potential harm is prolonged psychosis, which can occur during or after ingestion and can last for days and, in some cases, months in patients who suffer from premorbid mental illness such as schizophrenia and/or psychosis prior to ingestion of the hallucinogen. It is therefore not surprising that patients with such a predisposition are excluded from current trials of psychedelics. Finally, they present some safety guidelines for a rare disorder that can be caused by hallucinogenic substances, called persistent perceptual disorder (HPPD) in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR). The criteria for this disorder require that a hallucinogen user re-experiences perceptual effects similar to those experienced under acute hallucinogen exposure after cessation of hallucinogen use, that these effects are clinically distressing or impair functioning, and that they cannot be explained by a medical condition, another mental disorder, hypnopompic hallucinations, or other conditions better explained by mental disorders.

3.1 Addressing Smith and Sisti’s Arguments

Smith and Sisti argue that the personality changes induced by psychedelics differ in both their nature and magnitude from those produced by conventional psychiatric interventions. In
particular, they mention an increase in the traits of extraversion and openness to experience as measured by the Five-Factor Model of personality. This is supported by research suggesting that psychedelics have the unique ability to promote pro-social behavior, increase creativity, and facilitate a sense of openness and curiosity. These effects differ from the more subtle changes typically associated with psychiatric pharmaceutical interventions such as SSRIs or antipsychotics. Given the potential for significant alterations in personality, Smith and Sisti emphasize the importance of providing a more comprehensive informed consent process that explicitly addresses these changes, since such an enhancement to the informed consent may increase the probability of patients’ appreciating the possibility of personality change.

Furthermore, they emphasize the difficulty of communicating such information to the patient, arguing that it would be difficult to inform the patient of what to expect if the psychedelic experience is truly indescribable. In support of this argument, a process of enhanced informed consent is still vital despite the ineffable nature of psychedelic experiences. By providing information about the general tendencies and potential personality changes associated with psychedelics, therapists can set realistic expectations and help patients manage the transformative aspects of therapy. This includes discussing the potential effects on traits such as extraversion, openness to experience, and other aspects of personality, taking into account the patient’s own values and cultural background.

Duration of treatment: the authors emphasize the difference in treatment duration between typical psychopharmacological interventions and psychedelic therapies. Traditional psychiatric drugs often must be taken for a longer period of time before the full therapeutic effect occurs. This longer treatment period allows patients to gradually assess the benefits and potential risks associated with the drug. In contrast, psychedelics are known to produce a relatively rapid and intense effect with a single dose. This shorter time frame limits patients’ ability to think thoroughly about the potential implications and make informed decisions. Therefore, an enhanced informed consent process is necessary to ensure that patients are fully aware of the particular time constraints and potential consequences of psychedelic interventions. In support of their argument, given this time constraint, an enhanced informed consent process in psychedelic therapy becomes critical. It is important to ensure that patients are fully informed about the particularities of psychedelic interventions, including the accelerated time frame and potential consequences that may arise. Unlike typical psychotropic drugs, where the patient can discontinue treatment at any time, this option is not available with psychedelic therapy once the patient has taken the substance. By providing comprehensive information during the informed consent process, patients can better
understand and appreciate the distinct nature of psychedelic therapies so that they can make an informed decision about their participation.

Profound Experiences: Smith and Sisti argue that psychedelics can produce experiences that participants describe as profound, indescribable, and transformative. These experiences often involve a sense of unity, connectedness, and encounter with the ultimate truth or reality. Unlike traditional antidepressants, which are primarily aimed at symptom relief, psychedelics have the potential to produce profound changes in worldview and personal beliefs. Such experiences can have a lasting impact on an individual’s perceptions, values, and sense of self. Given the potential of these transformative encounters the authors argue, it is critical to provide enhanced informed consent that recognizes the uniqueness of these experiences and their potential impact on the overall well-being of the individual.

In addition, Smith and Sisti suggest that the (preparation phase) in psychedelic-assisted therapy should be considered an extension of the informed consent process. They argue that in addition to establishing a therapeutic relationship between participants and subjects, these sessions should also aim to provide participants with an in-depth discussion of the possible range of psychedelic experiences and advice on how to deal with difficult situations that might occur. I concur with this suggestion and emphasize the importance of an expanded informed consent process for the preparatory phase of psychedelic-assisted therapy. The integration of psychedelics into therapeutic practices holds great promise for the treatment of various mental illnesses but also presents unique challenges and risks that must be considered. During the informed consent process, participants are typically educated about the therapeutic process, potential benefits and risks, and possible alternative treatments. However, Smith, Sisti, and I argue that this phase should go beyond simply providing information and actively engaging participants in discussions about the range of possible psychedelic experiences. Psychedelics have the ability to induce profoundly altered states of consciousness that can lead to a wide range of experiences, including both positive and challenging ones. By preparing participants for this possibility, therapists can help them better process their experiences. This proactive approach not only mitigates potential harm but maximizes the therapeutic potential of these substances and most importantly gives that patient more time to make their decision.

While I welcome Smith and Sisti’s three reasons for the differences between these two types of drugs and that they justify the need for an enhanced informed consent, it seems to me that there are other differences that are relevant to the enhancement of informed consent. I will first list my reasons and then address each of them in detail.
1) The change in ethical values: this point is merely an extension of Smith and Sisti’s first reason (personality changes) and third reason (profound Experiences). As has been shown, psychedelic experiences can lead to significant changes in worldview and self-perception. Patients may have life-changing experiences that turn their previous ethical values, and worldviews upside down. While this may fall under (personality changes), I believe that an explicit distinction must be made between worldview changes and ethical value changes. The changes in worldview and ethical values, while interrelated, represent different aspects of personal transformation that may occur during or after the psychedelic experience and, accordingly, result in different types of harm of which the patient must be aware.

2) Set and setting: The mindset (set) of the user and the surrounding circumstances (setting) of the receiver have a significant impact on the effects of psychedelics. The patient’s psychological readiness, emotional state, the objects in the therapeutic room/place, and the relation to the therapist can have a major impact on how well a psychedelic session goes. And accordingly, how a patient would interpret the insights of the psychedelic experience. Such information a crucial for the patient to be aware of.

3) Suggestibility: Typical antidepressants work primarily by increasing the availability of serotonin in the brain, which can affect a person’s mood and emotional state and help regulate mood and relieve symptoms of depression and anxiety. Psychedelics, on the other hand (despite the fact that the mechanisms of action in the brain are not yet fully understood), can amplify the effects of suggestion and influence, making individuals more open to accepting and integrating new ideas, beliefs, and perspectives during and after the psychedelic experience. This suggestibility may result from the altered state of consciousness and lead to profound changes in perception, dissolution of the ego, and greater emotional openness that is likely to affect the patient’s volition and accordingly autonomy for months after taking psychedelics. I will show now how these three factors are fundamental to the informed consent and should be considered in the discussion of the enhancing it.

3.2 Changes in Ethical Values

Smith and Sisti contend that, when it comes to changes in values and personality, there are two significant concerns to take into account. First, if a person’s newly acquired values conflict with their pre-existing ones, some of the personality changes already outlined may be unwanted to them. For instance, non-spiritual or atheist patients may feel a loss if they obtain
a newfound feeling of spirituality or faith in God, especially if it goes against their preconceived notions or causes them to lose their social connections. Similar to this, religious patients who consider mystical experiences to be the product of devoted spiritual labor or a heavenly gift may suffer difficulties if they come to feel that these experiences are primarily driven by physiological factors as a result of receiving therapy. Second, it might be difficult to describe the intensity and transformative consequences of psychedelic experiences during consent discussions due to its ineffable nature and potential for personality changes. I share Smith and Sisi concerns, and yet I believe that the discussion can be extended to include another concern which necessitate a distinction between worldview changes and ethical value changes since they represent different aspects of personal change and with different consequences.

Changes in worldview refer to shifts in the way people perceive and interpret the world around them. This may include alterations in beliefs, attitudes, and perspectives regarding various aspects of life, such as spirituality, interconnectedness, the nature of reality, or the meaning and purpose of existence. Psychedelics can cause profound changes in perception that lead individuals to question and re-evaluate their previous understanding of themselves and the world. On the other hand, changes in ethical values pertain to alterations in moral principles, ethical frameworks, and judgments about what is right or wrong, good or bad. Psychedelic experiences can evoke a deep sense of interconnectedness, empathy, and compassion, which may influence moral perspectives and behaviors. People may develop a heightened sensitivity to ethical considerations, re-examine their values, and experience a reorientation toward greater integrity, empathy, and social responsibility. It is important to note that these changes may vary from person to person and are influenced by several factors, such as set and setting (see next section), personal beliefs, past experiences, and the context in which the psychedelic experience takes place. In addition, the nature and extent of these changes may be influenced by integration practices, support, and ongoing reflection following the psychedelic experience. I make the claim here that such a departure from ethical values might lead to what I suggest calling “Ethical Limbo”. Ethical limbo refers to a state of uncertainty or ambiguity regarding the ethical implications or consequences of a particular action, decision, or situation due to conflicting ethical principles caused by profound sudden experiences. It occurs when there is a lack of clear ethical guidelines and/or when individuals hold conflicting moral views. In the state of “ethical limbo”, it can be difficult for individuals to make morally defensible decisions because of either the lack of clear ethical principles or the presence of conflicting ethical values. The lack of clearly defined ethical principles and/or
the presence of conflicting values makes it very challenging for them to make morally
defensible decisions. The effects can be psychologically agonizing, as each ethical
consideration they face since the psychedelic experience leads to cognitive dissonance. In the
realm of “Ethical Limbo”, actions and decisions fall into a gray area where the boundaries and
implications of ethics become unclear, indeterminate, and contradictory. This uncertainty may
lead to significant psychological distress.

To illustrate the concept of “Ethical Limbo”, consider the following examples. Prior
to the therapy, the patient lived their life as a capitalist, believing that maximizing profit is the
highest ideal for society. This belief system informed their ethical principles and decision-
making processes. However, during the psychedelic experience, they undergo a
transformative encounter that transcends their previous understanding of reality. The profound
mystical encounter they experience may involve a sense of interconnectedness, unity, and
transcendence that goes beyond materialistic and profit-driven perspectives. This encounter
could bring them face-to-face with the limitations of their previous worldview, prompting a
re-evaluation of their ethical values and principles. As a result, the patient finds themselves in
a state of Ethical Limbo. The previously held belief in profit maximization as the highest ideal
for society now conflicts with the insights gained from the psychedelic experience. They may
question the ethical implications of prioritizing profit over the well-being of individuals and
the planet. This newfound awareness challenges the patient to reconsider their values and
principles. They may grapple with reconciling their previous capitalist beliefs with the
recognition of the interconnectedness of all beings and the need for a more compassionate and
sustainable approach to society. The patient may experience significant psychological distress
as they navigate this Ethical Limbo. They may face internal conflicts, questioning the
foundations of their previous ethical framework and struggling to align their newfound
insights with their previous belief system.

Consider now a patient with a strong religious background undergoing psychedelic-
assisted therapy. Their religious beliefs have provided them with a moral compass and a
framework for ethical decision-making throughout their life. However, during the psychedelic
experience, they experience transformative and profound insights that challenge their
established religious beliefs. These encounters may include experiences such as ego
dissolution, interconnectedness, or mystical states that transcend their previous understanding
of their beliefs. The patient may question their religious teachings and find themselves in a
state of ethical limbo, struggling with conflicting ethical values. The psychedelic experience
may raise ethical dilemmas that are difficult to reconcile in the context of their religious
beliefs. They may encounter contradictions between their religious teachings and the insights gained during the psychedelic experience, causing a sense of cognitive dissonance and accordingly psychological distress. For example, the patient’s religious teachings may emphasize strict adherence to a particular moral code, whereas the psychedelic experience reveals a more fluid and interconnected understanding of morality. This contrast may lead to internal conflict and confusion about how to navigate their ethical decision making in the future.

However, it must be mentioned the ethical limbo state is not inevitable. While changes in worldview and ethical values may be interconnected, it is also possible for someone to experience changes in their worldview without significant changes in their ethical values, or vice versa. For example, a person may develop a broader worldview but retain his or her existing ethical principles, or he or she may experience profound changes in his or her ethical values without a radical change in his or her overall worldview. Imagine an individual undergoing psychedelic therapy who gains a deeper appreciation for the interconnectedness of all life and the environment. This newfound understanding expands their worldview, making them more conscious of environmental issues and the need for sustainability. However, their core ethical principles of honesty, compassion, and respect for others remain unchanged. They continue to prioritize these values in their interactions and decisions, aligning their expanded worldview with their existing ethical framework.

Informed consent is a critical ethical and legal requirement for medical interventions, including psychedelic therapy. It ensures that individuals have the information and understanding necessary to make autonomous decisions about their participation in a treatment or research study. Creating transparency and fostering trust in the informed consent form processes are essential to building trust between the provider and the therapist and protecting the integrity of the process (Dickert et al. 2017). Recognizing the distinction between changes in worldview and changes in ethical values brought about by psychedelics and incorporating this understanding into the enhance informed consent process is therefore critical to upholding the principles of autonomy, respect, and patient-cantered care in psychedelic-assisted therapy. This ensures that patients have the information and agency necessary to make informed decisions that are consistent with their values and aspirations that might lead to a profound change to every aspect of their lives.
3.3 From Set and Setting to Active Super Placebo

The phrase “set and setting” was first introduced by psychologist Timothy Leary (Leary et al., 1963) and is now used in psychedelics research (Hartogsohn, 2016) to explain how psychological and environmental factors can influence a person’s response to psychedelics. Since the 1960s, it has been understood that psychological (internal) factors such as mood, expectancy, and intention, in addition to physiological effects, directly influence a person’s experience with a hallucinogen. The “set” is the term used to describe these psychological components. In addition to pharmacological and psychological factors, the environment-including physical, social, and cultural (external) factors also affects how a person responds to hallucinogens. The term “setting” refers to these factors (Hartogsohn, 2016). These factors play a critical role in shaping the subjective experience of hallucinogens and should be considered in the context of informed consent for psychedelic-assisted therapy. In their 2022 article “Culture, context, and ethics in the therapeutic use of hallucinogens: Psychedelics as active super-placebos?” David Dupuis and Samuel Veissière address an important issue when it comes to the therapeutic use of psychedelics. They acknowledge that there is widespread agreement among academics about the benefits of this psychedelic pharmaceutical “revolution”. However, they call for caution that the uncritical acceptance, desirability, and medicalization of these substances are still not fully understood, especially as they move further and further away from their “traditional” ritual and spiritual context (Dupuis & Veissière, 2022). They propose that hallucinogenic effects can be viewed as what they refer to as “active super-placebos”, defined as “an effect of substances that enhance ritual, symbolic, and interpersonal therapeutic processes by increasing suggestibility and the influence of extra-pharmacological, (non-specific) factors” (Dupuis & Veissière, 2022, p.571). They contend that the therapeutic benefits of these substances stem not only from their chemical composition, but also from the relationship with the therapist, the social interactions, and the cultural context that shape both the relationship with hallucinogenic experiences and their phenomenological content, as they can trigger the placebo effect via cultural and environmental variables. They note that psychedelic encounters typically involve an aspect of meaning- crystallization and enculturation into contextually mediated assumptive worlds (or ideologies) and behaviors that may lead to unfavourable outcomes due to their ability to increase suggestibility.

Consideration of the interplay of setting, setting, and cultural context in discussions about informed consent for psychedelic-assisted therapy is critical. When these factors are
considered, health care providers can better prepare their patients for the experience and optimize therapeutic outcomes. Respect for patients’ values and cultural backgrounds is essential to patient-centered care. Each person brings their unique cultural perspectives, beliefs, and values to the therapeutic process. By considering the set, setting, and cultural context, these different backgrounds are acknowledged and respected, ensuring that therapy is sensitive to and appreciates the patients’ cultural and value systems. By incorporating these factors into informed consent discussions, therapists demonstrate their commitment to understanding and valuing the patients’ perspectives, fostering a therapeutic relationship based on trust and mutual respect. This comprehensive approach to informed consent recognizes the multifaceted nature of psychedelic therapy, incorporating psychological, environmental, and cultural dimensions. Recognizing the influence of these factors in the informed consent process is consistent with the evolving understanding of psychedelics and their potential therapeutic benefits. It allows for a more holistic approach that considers not only individual psychological factors and the immediate environment, but also the broader cultural context in which therapy takes place. By incorporating this understanding into informed consent discussions, therapists demonstrate their commitment to tailoring treatment to the patient’s care and promoting concordance with participants’ values that respects and considers the complexity of the psychedelic experience.

3.4 Suggestibility

The term ”suggestibility” is usually operationalized as an increased tendency to accept and act on the ideas or attitudes of others (Sjöberg & Hollister, 1965). The term ”suggestion” is defined by Dupuis and Veissière (2022) ”as a process of decreased effortful control and increased susceptibility to contextual factors-rather than a discrete psychological trait (e.g., hypnotic suggestibility)-including but not limited to framing effects, verbal and non-verbal suggestions, peer influences, etc.” (p.573). Unlike typical SSRIs, the altered states of consciousness induced by psychedelics may lead to increased susceptibility and suggestibility. Psychedelics can enhance the effects of suggestion and influence so that people are more open to accepting and integrating new ideas, beliefs, and perspectives during the psychedelic experience (Dupuis & Veissière, 2022).

The increased suggestibility associated with psychedelics may carry both potential benefits and risks. On the one hand, it can facilitate therapeutic processes by allowing individuals to explore and adopt new perspectives, insights, and behaviors that can promote...
personal growth, emotional healing, and positive change. This suggestibility can increase the effectiveness of psychedelic-assisted therapies, in which the therapeutic process often involves deep introspection, emotional processing, and integration of new insights. However, increased suggestibility also raises ethical concerns and requires careful guidance and support during and after the psychedelic experience. This underscores the importance of informed consent and the role of health care providers in ensuring that suggestions provided during the experience are consistent with the patient’s values, goals, and well-being. Safeguards must be in place to prevent possible manipulation or undue influence by suggestions that may not be in the best interest of the individual. In addition, the patient must be aware that the effects of suggestion may last for months and may significantly influence his or her decision making leading to a compromise of their autonomy and self-determination. By clearly outlining the potential risks, benefits, and alternatives, enhanced consent procedures help patients understand the potential impact of psychedelics on their thinking and receptivity to suggestion. Informed consent must provide the opportunity to educate patients about the potential effects of psychedelics on their suggestibility and enable them to make an informed decision that fits with their values and life condition.

1) Personality changes  
2) Duration and immediacy of effects  
3) The nature and intensity of subjective experiences  
4) Changes in ethical values  
5) Set and setting  
6) Suggestibility

When using psychedelics in therapy, informed consent should be thorough and take into account the multifaceted nature of these experiences. Therapists demonstrate their dedication to patient-centred care, respect for autonomy, promoting concordance with participants’ values, transparency, and the complexity of the psychedelic experience by incorporating these factors into the informed consent procedure. This strategy promotes openness, builds trust, and empowers people to make decisions that are consistent with their values and goals and impact every aspect of their lives. Now that we have discussed all the reasons for enhancing consent, let us turn to the possible objections to my proposals.
4. Possible objections

4.1 Objection to the Changes in Ethical Values Argument

A possible counterargument to the notion of “ethical limbo” resulting from changes in ethical values due to psychedelic experiences is the assumption of a binary and static understanding of ethical principles. In reality, ethical frameworks and moral judgments are not rigid and universally accepted. They evolve and can be influenced by various factors such as cultural, social, and personal contexts. The argument put forward above suggests that sudden and profound experiences through psychedelics may lead to conflicting ethical principles and a lack of clear guidelines for moral decision-making. However, this view overlooks the inherent complexity and flexibility of ethical reasoning. Ethical dilemmas and conflicting values are not unique to psychedelic experiences but are also found in other areas of life where individuals are constantly confronted with the nuances of right and wrong, good and evil. Moreover, it is assumed that individuals must adhere to a single set of ethical principles and that any deviation from these principles will inevitably lead to some sort of psychological distress. However, individuals often hold multiple ethical frameworks and principles simultaneously, which allows for consideration of different perspectives and a more nuanced approach to decision-making. Someone can change their ethical values without falling into a state of uncertainty or psychological distress. Furthermore, the potential for integration practices, support, and ongoing reflection following a psychedelic experience is not adequately addressed in this argument. These post-experience processes of the thereby can help individuals reconcile conflicting values, engage with ethical exploration, and find new ways to navigate the complexities of their evolving ethical landscape. The argument assumes a static state of “ethical limbo” without considering the potential for growth, adaptation, and resolution that humans have.

Psychedelic experiences can indeed lead to changes in ethical values, but the notion of an “ethical limbo” as a universal and inevitable consequence is overly simplistic. Ethical frameworks are dynamic and subject to personal interpretation and evaluation. Individuals can manage ethical dilemmas, reconcile conflicting values, and adjust their new moral perspectives through ongoing reflection and integration practices, especially when supported by ethical guidelines. This objection to the argument is legitimate, but two points should be noted: First, Smith and Sisti’s broad definition of personality “the narrative features and values of an agent that make them a distinctive (type of) person” (Smith & Sisti, 2020, p.808) may blind the therapist from recognizing potential psychedelic effects on a person’s ethical
values. In addition, it might not be clear to the patient what changes in personality and worldview mean. Second: Although the idea of an “ethical limbo” may seem oversimplified and underestimates the complexity of ethical reasoning and perhaps people’s ability to reconcile competing ethical values, it does not imply that this state is inevitable nor that it is universal, but rather illustrates how deviating from the patient’s ethical framework “may” result in “ethical limbo”. Furthermore, it highlights a fundamental aspect of change that can occur in people’s lives, of which they should certainly be aware before deciding to go through the process and alert the therapist to consider this aspect during the integration phase.

4.2 Objection to the Set and Setting Argument

Although it is important to consider the psychological, environmental, and cultural dimensions of informed consent for psychedelic-assisted therapy, there is a risk that patients’ expectations may be inadvertently influenced if detailed information about the set, setting, and cultural context is provided in the informed consent process. The phenomenon of expectancy, in which individuals’ beliefs and expectations shape their experiences, plays a significant role in the subjective effects of psychedelics (Butler et al., 2022). Expectancy effects have been observed in psychedelic research. Studies have shown that the information provided before and during a psychedelic experience can significantly influence an individual’s perceptions, emotions, and overall outcomes. Thus, the counterargument here would be that by discussing set, setting, placebo effect, and cultural context in detail during the informed consent process, healthcare providers risk raising certain expectations or biases in patients that could affect their subjective experiences, thus overshadowing the authentic experience and impeding the therapeutic process.

A possible response to this counterargument would be that cultural narratives, media representations, and social influences are factors that affect the patient’s expectations before the therapy has even occurred. Cultural narratives, media representations, and social influences play an important role in shaping people’s beliefs and expectations about psychedelics even before they enter therapy. Through various channels such as movies, books, news articles, and online discussions, people are exposed to representations of psychedelic experiences that are often linked to their own biases, stereotypes, and misconceptions. These cultural narratives can lead to preconceived notions about what a psychedelic experience should be like and what outcomes should be expected. For example, psychedelic experiences are often sensationalized or exaggerated in the media, with an emphasis on visual beautiful
geometrical hallucinations, and extreme mental states. Such portrayals may lead people to
develop unrealistic expectations about the intensity or nature of the psychedelic experience.
On the other hand, cultural narratives rooted in traditional rituals or spiritual contexts may
emphasize the mystical or transformative aspects of psychedelics and shape expectations of
deep insights or spiritual revelations. In addition, social influences are another important
factor contributing to the formation of expectations. People may hear anecdotal stories or
receive accounts from friends, acquaintances, or online communities about their own
experiences with psychedelics. These narratives, whether positive or negative, can
significantly influence people’s expectations and beliefs about what they might encounter
during therapy.

To ensure a comprehensive understanding, healthcare providers should take the
time to have meaningful conversations about the set, setting, and cultural context during the
informed consent process. This includes exploring the patient’s mindset, discussing and
evaluating their preconceived expectations, addressing concerns about the immediate
environment, and considering the cultural factors that may influence the patient’s experience.
For example, a patient who is aware of these factors may want to bring the picture of his or
her father because it makes him/her feel safer, or a patient with a Christian background may
want to bring the cross, etc. Failure to adequately address these dimensions during informed
consent may result in a limited understanding of the potential implications and considerations
that arise from the individual’s cultural background. By devoting adequate time and attention
to these factors, healthcare providers can help patients develop a more nuanced understanding
of the potential influences on their psychedelic experiences and correct misconceptions that
may have already shaped their expectations.

4.3 Objection to the Suggestibility Argument

This argument highlights the potential risks associated with increased suggestibility during
and after the psychedelic experience and raises ethical concerns regarding the manipulation or
undue influence on vulnerable individuals. However, one might object that suggestibility is
not solely induced by psychedelics but exists within a broader psychological context and can
be influenced by many other factors. Ultimately, suggestibility is a psychological trait that
varies among individuals and can be influenced by various factors, including personality
traits, social conditioning, and cultural influences. It is not exclusive to psychedelic
experiences. Suggestibility is present in everyday life and can be observed in various contexts, such as advertising, peer pressure, and societal norms.

While it is true that suggestibility is not unique to psychedelics but occurs in a variety of contexts, including daily life, it is important to consider the particular implications of increased suggestibility in psychedelic experiences when we discuss enhanced informed consent due to the unique nature of the subjective effects of the psychedelic experience. The unique nature of psychedelic substances and their potential to significantly alter a person’s perception and thought processes distinguishes them from other situations in which suggestibility is an issue. Unlike everyday life situations, psychedelic experiences can induce intense experiences associated with an increase in empathy and compassion and profound changes in consciousness, usually associated with spiritual and religious interpretations, leading to a heightened state of receptivity and openness to suggestion. Thus, they differ from all other external factors that might induce suggestibility such as the media or advertisement. It may be possible to identify individual differences in susceptibility to suggestion, and this is indeed an important aspect to keep in mind. Nevertheless, I shall argue the altered states of consciousness induced by psychedelics have the potential to increase receptivity to suggestion in all people, regardless of their baseline level of susceptibility. While some people are naturally more receptive to suggestions than others, the content of the subjective effects of the psychedelic experience is a significant factor that may increase suggestibility in ways that go beyond individual differences.

This heightened suggestibility during and after the psychedelic experience can have long-lasting effects on a person’s beliefs, attitudes, behaviors and accordingly, autonomy and self-determination. Therefore, it is crucial to consider this increased suggestibility so that patients can make informed decisions. Enhanced informed consent procedures should consider the potential risks associated with the increased suggestibility induced by psychedelics in the context of the uniqueness of the subjective effects of the psychedelic experience that sets them apart from many other factors that might influence suggestibility.
5. Conclusion

In summary, after introducing the topic and providing background from empirical research, I have reviewed and supported Smith and Sisti’s three reasons why psychedelic substances (particularly psilocybin in the case of their paper) should not be treated like typical psychotropic drugs in terms of informed consent. I then turn to a discussion that highlights the potential impact of psychedelic experiences on changing ethical values and the concept of “ethical limbo” that may arise as a result of the psychedelic experience. I show that changes in worldview and ethical values, while related, represent different aspects of personal change and can have different consequences. Psychedelic drugs can lead to altered perceptions and interpretations of the world (changes in worldview) as well as changes in moral principles and judgments of right and wrong (changes in ethical values). These changes may vary from person to person and are influenced by a variety of factors, including environment, personal beliefs, past experiences, and integration practices. This state of ethical limbo can be psychologically distressing as it leads to cognitive dissonance and the implications of ethical values become unclear, indeterminate, and contradictory for the patient. The discussion emphasizes the importance of considering the interplay of set, setting, and cultural context in the process of informed consent. By acknowledging and respecting patients’ cultural perspectives, beliefs, and values, therapists can tailor treatment to individual needs, promote patient-cantered care, and foster a therapeutic relationship based on trust and mutual respect. In addition, the discussion raises awareness of the increased suggestibility associated with psychedelics and the need for safeguards to ensure that suggestions provided during the experience are consistent with the patient’s values and well-being. Informed consent for psychedelic-assisted therapy becomes crucial in light of these considerations. Overall, an enhanced informed consent process that takes these factors into account allows individuals to make informed decisions that are consistent with their values and needs, especially if the informed consent process is extended to the preparation phase. Such a strategy promotes transparency, respects autonomy, is appetitive of patients’ values, gives them time and knowledge they need to make informed decisions, and acknowledges the multifaceted nature of the psychedelic experience and its long-term effects on patients.

Finally, the results of the cited empirical studies are still preliminary and should be interpreted in light of the following limitations. Only studies that were written in English were included. The small sample size of participants, which ranged from 10 to 43 in all included studies, raises doubts about the reliability of the statistical significance of the results. Different
studies used different subjective rating scales to assess the subjective effects of the psychedelic experience, making expectancy bias possible. In most of these studies, the subjective rating scales were administered to participants approximately 7-8 hours after ingestion, although by this time the main effects of the substance have worn off, some of the effects persist longer. However, the research is clearly indicating that psychedelic substances have the potential to improve and save the lives of millions of people, and perhaps even provide a solution to the environmental and political challenges facing humanity as a whole. A topic that requires the attention of ethicists in general and bioethicists in particular to examine the ethical implications for the administration of these substances and to provide ethical certainty to researchers, therapists, and policy makers to prevent possible harm that could hinder research in this mysterious and highly beneficial area of life.
References


