

Submission Date: December 9, 2016

Tri Council Policy Statement (TCPS 2) Tutorial Date: November 10, 2015

Most recent review of REB FAQs Date: October 2, 2016

1. RESEARCH TEAM

1.1 Research Title

A Thematic Analysis of Pre- and Post-Ceremony Factors Related to Self-reported Therapeutic Value of Ritualized Ayahuasca Use Among Canadians

1.2 Applicant (Student Researcher or Principle Researcher)

Name: Melanie Nicole Magueta Oliveira Phone: ----- Email: -----
Program: Doctor of Psychology in Clinical Psychology (Psy.D)

1.3 Co-Principal Researcher(s) or Faculty Supervisor (Supervising Researcher)

Name: Dr. Anna Khaylis Email: akhaylis@adler.edu

1.4 Research Team Members (Investigators/Second Reader/Committee Members/Consultants)

Name: Dr. Gerald Thomas Email: ----- Affiliation: UBC

Name: Dr. Michael Mandrusiak Email: Mmandrusiak@adler.edu Affiliation: Adler University

1.5 Research Team Experience

APPLICANT:

Melanie Oliveira will be conducting this study as part of the qualification criteria for her Doctor of Psychology in Clinical Psychology (Psy.D.) degree. She has a Bachelor of Science (Honours) with Distinction from the University of Toronto. She completed a research methods course at Adler University, University of Toronto and Athabasca University, and learned about qualitative research methods, including Thematic Analysis, which she will be using in this proposed study. Melanie has conducted extensive literature reviews for various class projects exploring the therapeutic effects of ayahuasca and proposed mechanisms of its healing potential (Freckska, Bokor, & Winkelman, 2016; Labate & Cavnar, 2014; Loizaga-Velder & Pazzi, 2014; Thomas et al., 2013). She also attended the Spirit Plant Medicine Conference at the University of British Columbia in October 2015, where she learned about the current state of research and clinical practice using spirit plant medicines, including ayahuasca.

RESEARCH TEAM:

Dr. Anna Khaylis is a core faculty member at Adler University and the dissertation chair of the proposed study. Her clinical training and practice has focused on the assessment, treatment and



research of trauma-related disorders. Given that research suggests ayahuasca can treat post-traumatic stress symptoms and help individuals process and reconcile traumatic experiences (Loizaga-Velder & Pazzi, 2014; Nielson & Megler, 2014; Prickett & Liester, 2014), her clinical knowledge and research on trauma will provide valuable insight in this study.

Gerald Thomas is a Collaborating Scientist with the Centre for Addictions Research of BC at the University of Victoria, and an adjunct professor at the University of British Columbia. He received his Ph.D. in political science from Colorado State University in 1998 and has worked in the area of addiction policy since 2004. Dr. Thomas has extensive knowledge and expertise in spirit plant medicine. For example, between 2011 and 2013 he led a research project with Dr. Gabor Mate to investigate the effectiveness of ayahuasca-assisted therapy for treating stress and addiction with members of a First Nations band in BC (Thomas et al., 2013). He and his colleagues presented the findings of this study at the Psychedelic Science Conference in April 2013. Dr. Thomas was also a presenting speaker at the Spirit Plant Medicine in October 2015. Taking knowledge from neuroscience and shamanism, he discussed a novel understandings of how entheogens work to facilitate deep, sustainable healing preparation. He also spoke about the importance of preparation and integration for deepening one's spiritual development and healing (Thomas, 2015).

Dr. Michael Mandrusiak is the Director of Training and core faculty at Adler University. He has varied research interests, one being the integration of clinical treatment with client religion and spirituality. Ayahuasca has traditionally been used in sacred healing rituals for divination and spiritual purposes, and its existential-derived insights bring about positive improvements in health (Schmid, 2014; Trichter, 2010). As such, Dr. Mandrusiak's research on the role of spirituality on mental health will provide a valuable framework from which to conceptualize possible spiritual-therapeutic effects of ayahuasca in the proposed study. Additionally, his knowledge of methodology and ethical research practices will be invaluable.

1.6 Research Support Members (if applicable)

A student research assistant will be recruited to help transcribe the data and later provide an external audit to validate the results. The student will have completed a graduate level research methods class, and will have completed the TCPS-2 tutorial.

2. SUMMARY OF STUDY AND RECRUITMENT

2.1 A. Overview of Research Study (Maximum 300 words)

Summarize the research proposal using the following headings 1) Purpose, 2) Research Question or Hypothesis, 3) Rationale, 4) Objectives

1) Purpose:

To explore perceived therapeutic effects of ayahuasca and how pre- and post-ceremony factors influence the depth and sustainability of these effects. [Ayahuasca is a spirit plant medicine used for thousands of years for personal and collective healing by indigenous peoples in the Amazon. It is a psychedelic tea made from boiling two plants: the Banisteriopsis caapi and Psychotria viridis bush. (Frecka et al., 2016).]

2) Research Questions:

- What are the subjective experiences and healing effects of ayahuasca?
- How do individuals or clients best prepare for and integrate their ayahuasca experience into their everyday lives?
- How do these preparation (pre-ceremony) and integration (post-ceremony) factors influence the depth and sustainability of therapeutic outcomes?

3) Rationale:

The ritualized use of ayahuasca can facilitate therapeutic experiences for some people and some conditions such as addictions, anxiety, and depression (Labate & Cavnar, 2014).

Increasing numbers of Westerners are participating in ayahuasca ceremonies for spiritual and emotional healing purposes or personal and spiritual development (Freckska et al., 2016; Tupper, 2011; Winkelman, 2005). While some report beneficial or therapeutic outcomes, other Western users may find their ayahuasca experience confusing, disorienting, and difficult to integrate (Kaufman 2015; Trichter, 2010).

It is suggested that Westerners require qualified assistance from therapists to therapeutically support their ayahuasca experience pre- and post-ceremony (Freckska et al., 2016; Kavenská & Simonová, 2015; Lewis, 2008; Trichter, 2010), but given the illegality of ayahuasca in Canada, the number of therapists familiar with its effects is generally very low, thus professional assistance may be inadequate (Freckska et al., 2016). As such, it is important that pre- and post-ceremony factors that may impact healing be identified and translated into practical guidelines for mental health professionals to protect the physical, psychological and spiritual health of Western clients who have used or planning to use ayahuasca for healing purposes (Trichter, 2010).

4) Objectives:

This study will identify common themes in the therapeutic potential and risks of ayahuasca, and help develop evidence-based guidelines for mental health professionals to support clients who have used, or planning to use, ayahuasca for healing purposes.

2.1 B. Summary of Research Procedures (Maximum 500 words)

Describe in a step-by-step manner the research procedures. The description should include the research methodology (e.g., ethnography, action, narrative, survey), rationale for utilizing this methodology, population, sampling method (e.g. convenience, key informant, snowball), group assignment strategies (e.g., random, by education level, geographic location, age), type of research methodology (e.g., ethnography, action, narrative, survey), analytic strategies, dissemination strategies.

- 1) The proposed study will utilize purposeful sampling of participants best suited to providing rich data that effectively answers the research questions. The Recruitment Inquiry Letter (Appendix A) will be emailed to confidential ayahuasca communities in British Columbia. These members will be asked to share the Recruitment Posters for Ayahuasca Users (Appendix B) and Ayahuasca Ceremony Leaders (Appendix C) with interested individuals who may meet participation criteria. Recurrent ayahuasca users are being recruited to speak about their



various encounters with ayahuasca. Ceremony leaders are recruited to obtain professional knowledge regarding its use.

- 2) Once potential participants email the student researcher, she will respond using the Initial Participant Contact Script (Appendix D) to arrange a brief phone interview. Phone Scripts (Appendices E and F) will be used to determine eligibility, describe the research purpose and participation process if eligibility is met.
- 3) The Informed Consent Form will be emailed to interested individuals who meet criteria (Appendices G and H). These individuals will be asked to contact the student researcher within a week to inform if they will or will not participate.
- 4) Initial interviews will be arranged with participants at mutually agreed, confidential locations. The consent form will be reviewed and signed at the initial meeting.
- 5) The student researcher will then use a semi-structured interview developed by the research team (Appendix I and J). Semi-structured interviews offer the most effective and flexible way of collecting data for qualitative studies (Creswell, 2012). At the in-person interview, the student researcher will review the Informed Consent Form with potential participants, assess their capacity to provide consent, and provide a list of resources in case they become distressed. Participants will be asked to adopt a pseudonym throughout their interviews to protect their identity. Each interview is approximately 1 – 2 hours.
- 6) The interviews will be audiotaped and transcribed for data analysis. Audio recordings will be immediately transferred into an encrypted computer folder. Transcriptions will be stored on encrypted Word documents.
- 7) An essentialist/realist thematic analysis will be used to identify, analyze, and report patterned responses and meanings in the data set. Given that the student researcher is interested in analyzing core themes in healing effects of ayahuasca and pre- and post-ceremony variables that subjectively impact treatment outcomes, a thematic analysis is most appropriate to answer these research questions (Braun & Clarke, 2006). This analysis provides a theoretically and methodologically sound way of systematically analyzing how individuals make sense of a particular phenomenon and identifying common themes across these experiences (Braun & Clarke, 2006). Braun and Clark's (2006) 15-item checklist will be utilized to ensure that this thematic analysis is of good quality.
- 8) Unrecorded participant validation check interviews (Appendix K) will occur over the phone and last approximately thirty minutes to an hour.
- 9) The student research assistant will conduct an external audit to validate results.

2.2 References

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3, 77–101. doi:10.1191/1478088706qp0630a

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2014. Retrieved from http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf

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- Frecska, E., Bokor, P., & Winkelman. (2016). The therapeutic potentials of ayahuasca: Possible effects against various diseases in civilization. *Frontiers in pharmacology*, 7.
- Kaufman, R. (2015). *How might the ayahuasca experience be a potential antidote to western hegemony: A mixed methods study* (Doctoral dissertation, Fielding Graduate University).
- Kavenská, V., & Simonová, H. (2015). Ayahuasca tourism: participants in Shamanic rituals and their personality styles, motivation, benefits and risks. *Journal of psychoactive drugs*, 47(5), 1-9.
- Labate, B. C., & Cavnar, C. (Eds.). (2014). The therapeutic use of ayahuasca. Springer Berlin Heidelberg.
- Lewis, S. E. (2008). Ayahuasca and spiritual crisis: Liminality as space for personal growth. *Anthropology of Consciousness*, 19(2), 109-133.
- Loizaga-Velder, A., & Pazzi, A. L. (2014). Therapist and patient perspectives on ayahuasca-assisted treatment for substance dependence. In B. C. Labate & C. Cavnar (Eds.), *The therapeutic use of ayahuasca* (pp. 133-152). Springer Berlin Heidelberg.
- Nielson, J. L., & Megler, J. D. (2012). Consideration of ayahuasca for the treatment of posttraumatic stress disorder. *MAPS Bulletin Annual Report*, 29-31.
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- Schmid, J. T. (2014). Healing with ayahuasca: Notes on therapeutic rituals and effects in European patients treating their diseases. In B. C. Labate & C. Cavnar (Eds.), *The therapeutic use of ayahuasca* (pp. 77-93). Springer Berlin Heidelberg.
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- Thomas, G. (2015, October 24). Integrating understandings from neuroscience, shamanism and psychology on the role of spirit plant medicines and other psychedelics in deep, emotional healing. Paper presented at the Spirit Plant Medicine Conference: University of British Columbia.
- Trichter, S. (2010). Ayahuasca beyond the Amazon: The benefits and risks of a spreading



tradition. *Journal of Transpersonal Psychology*, 42 (2), 131-148.

Tupper, K.W. (2011). Ayahuasca in Canada: Cultural phenomenon and policy issue. In B.C. Labate and H. Jungaberle (Eds.), *The internationalization of ayahuasca* (pp. 319-325). Zurich: Lit Verlag.

Winkelman, M. (2005). Drug tourism or spiritual healing? Ayahuasca seekers in Amazonia. *Journal of Psychoactive Drugs*, 37(2), 209-218.

2.3 Inclusion Criteria

For Ayahuasca Users:

- Canadian Resident (all ethnic backgrounds are welcome);
- Speak English;
- Are 19 years or older;
- Participated in 5 or more ayahuasca ceremonies;
- Had different outcomes (i.e., some that were significant or deeply healing, while others were not);
- Want to speak about your experience using this tea;
- Want to speak about the practices used before and after ceremony;
- Can complete up to 3 hours of interviews within a one-year time frame;
- Live in the Lower Mainland or able to visit this area for one interview.

These inclusion criteria were selected because these participants can speak to their various encounters with ayahuasca. They can describe their deepest, most intense and sustained healing outcomes and discuss how they prepared for and integrated those experiences (i.e., describe the rituals, practices, or procedures used before and after ceremony, respectively). They can also describe other instances where deeper healing did not occur, or when therapeutic effects were minimal, and the pre- and post-ceremony practices associated with those experiences. Speaking from their personal experience, they can also describe the perceived benefits and risks of ingesting ayahuasca ceremonially. Also, the student researcher is English speaking and does not have access to interpreters. Lastly, there is minimal research on ayahuasca using a child population.

For Ayahuasca Ceremony Leaders:

- Speak English
- Are 19 years or older;
- Received qualified training as a shaman, neo-shaman, or curandero in the ritual or ceremonial use of ayahuasca;
- Led 20 or more ceremonies after completing training;



- Want to speak about your experience using this tea with clients;
- Want to discuss practices used with clients before and after ceremonies;
- Can complete up to 3 hours of interviews within a one year time frame;
- Live in the Lower Mainland or capable of visiting this area for one interview

These inclusion criteria were selected because these participants can speak to their professional experience using ayahuasca with clients. For instance, they can describe their understanding of its perceived potential benefits and risks. They can also explain how the ritualized use of ayahuasca can be therapeutic or beneficial for some clients, yet less significant, minimally therapeutic, or unpleasant for others. Their expertise and knowledge can help inform the development of practical guidelines for other health care professionals to support clients.

2.4 Exclusion Criteria

For Ayahuasca Users:

- Self- identified history of psychosis and/or currently psychotic
- Active suicidality

These exclusion criteria were selected because ayahuasca is not recommended for individuals with suicidality and/or psychosis (Loizaga-Velder & Pazzi, 2014; Nielson & Megler, 2012).

For Ayahuasca Ceremony Leaders:

- Individuals currently in training as ceremonial leaders, whether as a shaman, neo-shaman, or curandero

This exclusion criteria was selected because ceremony leaders in training have minimal professional experience and cannot provide as much rich and varied data

Note: If the potential participant discloses current psychotic symptoms and/or suicidality during the screening process using the Phone Script for Potential Ayahuasca User Participants (Appendix E), the student researcher will provide him/her/they with the Crisis Line resource, outlined in the Informed Consent Form. Individuals that meet all exclusion criteria will be emailed a list of mental health resources (taken from the Informed Consent Form, Appendices G and H) via email.

2.5 Recruitment

- 1) Potential referral sources will be contacted by Dr. Thomas, a dissertation committee member whom has already established a trusting and respectful relationship with anonymous ayahuasca communities in British Columbia. Dr. Thomas will email the Recruitment Inquiry Letter (Appendix A) to members of these communities, kindly asking them to share recruitment posters (one for recruiting ayahuasca users and the other for ayahuasca ceremony leaders; Appendices B and C) with interested individuals who may meet participation criteria.
- 2) These recruitment posters introduce the research team, describe the research purpose,



participation process, inclusion criteria, and request interested individuals to contact the principle researcher via email.

- 3) When the student researcher receives an email from potential participants, she will respond using the Initial Participant Contact Email (Appendix D) to arrange a brief phone interview. During the screening process, Phone Scripts will be used to ensure that all relevant information is discussed (Appendices E and F). The student researcher will thank the individual for their interest, ask screening questions to determine eligibility, then describe the research purpose and participation process in greater detail, for those who qualify. The student researcher will thank those who do not meet criteria for their time and willingness to participate, briefly explaining that they do not qualify. They will be emailed a list of mental health resources (taken from the Informed Consent Form, Appendices G and H) via email.
- 4) At the end of the phone interview, the Informed Consent Form will be emailed to those who remain interested and meet criteria (Appendices G and H). These individuals will be asked to review the informed consent form before making a decision and contact the student researcher within one week to inform if they do, or do not, want to participate. If the student researcher has not heard from a potential participant within this time frame, she will follow up via email or phone, if the individual consents to this.
- 5) When potential participants contact the student researcher informing about their desire to proceed, an in-person interview will be arranged at mutually agreed, confidential locations.
- 6) At the in-person interview, the student researcher will review the Informed Consent Form with potential participants and assess their capacity to provide consent. Those who illustrate their understanding of the study and its benefits and risks can formally provide consent by signing the form. The audio recorded interview will then follow.

2.6 Access to Records for Recruitment

Are you accessing records to identify potential participants?

No

2.7 External Approvals

Outline how you will contact and then obtain external approval from institutions or organizations, including Aboriginal communities or international sites. Although approvals do not need to be included with your Application, the REB has an obligation to conduct ongoing ethical review. You may be asked to produce copies of all external approvals during the period in which you are conducting research.

Dr. Gerald Thomas has already established a trusting relationship with ayahuasca communities within B.C. On behalf of the research team, he will email the Recruitment Inquiry Letter (Appendix A) to members of these communities. This letter introduces the research team, purpose of the study, and kindly asks for their assistance in the recruitment process. Members will be asked to share the Recruitment Posters for Ayahuasca Users (Appendix B) and Ayahuasca Ceremony Leaders (Appendix C) with interested individuals who meet participation criteria.

2.8 Number of Participants

How many participants do you anticipate recruiting for your Research?

- 10 – 15 participants
- The majority of participants will be ayahuasca users given that a central aspect of this study is understanding the ayahuasca experience from a Canadian (or Western) clients' perspective
- Approximately 3 participants will be ayahuasca ceremony leaders

If part of a larger study, how many participants will be recruited overall?

- N/A

2.9 Deception:

Is deception being used in this research?

No

3. FUNDING INFORMATION & CONFLICT OF INTEREST

3.1 Source of Funding

N/A

3.2 Restrictions on Information Disclosures

N/A

3.3 Actual or Perceived Conflict of Interest

Do any Research Team Members or their immediate family members have past or current affiliation with an agency, institution, community, or individual that will provide assistance with recruiting sources or participants, data collection sites, participant populations or follow-up assistance for this research? This includes workplaces, volunteer organizations, practicum sites, and community-based groups.

- Yes

If yes, please explain the relationships between Research Team Members and the agency, institution, community, or individual in question and indicate how you plan to mitigate actual or perceived conflicts of interest or dual-relationships:

- There is a possibility of a dual relationship. Dr. Thomas, a dissertation committee member, has established a trusting and respectful relationship with confidential ayahuasca communities in British Columbia. He will notify these communities about the proposed study and kindly ask for their help in recruiting participants (Appendix A). Dr. Thomas will not interview participants; however, if he reviews transcriptions during the analytic process, it is possible that he might re-identify ceremony leaders given that the community is small. Dr. Thomas is aware of his ongoing responsibility to protect the confidentiality of all participants and will



sign the Research Team Confidentiality Agreement Form before the study commences. In addition, potential participants will be notified in the informed consent form about the potential for this conflict of interest before they choose to participate in this study (see Appendices G and H).

Do any Research Team Members or their immediate family members receive personal benefits (e.g. salary, overtime hours, consultant fees, or other financial gain) in connection with this research over and above the direct cost of conducting this study?

- No

If yes, please explain and indicate how you plan to mitigate actual or perceived conflicts of interest:
N/A

4. RISK LEVEL and RISK MANAGEMENT

4.1 Determining Level of Risk

Minimal

Rationale:

This research meets the requirements for a minimal risk study is because participants are from a non-clinical population and are self-selected based on their interest in talking about their experiences with ayahuasca. Prior to being interviewed, participants will be informed to share as much or as little as they feel comfortable with and to refrain from answering questions if they choose. The interviews will mainly be guided by the participants themselves with only minimal probing questions asked by the student researcher. It is possible that reflecting on these experiences may cause participants some distress. In such an event, the student researcher will discontinue the interview and refer them to seek support from the list of resources outlined in the Informed Consent Form (Appendices G and H). Given that the probability and magnitude of potential distress from participating in this study is no greater than what participants encounter in their everyday life (when talking about or reflecting on their ayahuasca experiences), this is a minimal risk study according to the policy of ethical conduct (Canadian Institute of Health Research, 2014).

Additionally, there is a small possibility that if participants' identities become compromised, they could face legal consequences for using or administering ayahuasca as these activities are presently illegal in Canada. Despite its legal status though, there is no history of clients or ceremony leaders legally persecuted in Canada for ayahuasca use or administration (Tupper, 2011). There has only been one legal case in Canada (*Regina v. Uyunkar*) but due to a client's death during ceremony, rather than the use or administration of ayahuasca (Tupper, 2011). In 2001, Juan Uyunkar, a shaman from Ecuador led a ceremony in Wikwemikong, Ontario and a woman expectantly died under his care. The coroner's report ruled that the cause of death was acute nicotine intoxication from tobacco used in ceremony. Her death was unrelated to ingesting ayahuasca. Uyunkar pled guilty and was sentenced to a year's community service in Wikwemikong (Tupper, 2011). Given the absent history of criminal



trials involving ayahuasca use or administration in Canada, there is a low likelihood of participants' exposure to risk of prosecution; participation in this study still meets minimal risk criteria. Nonetheless, precautions will be taken for participants to remain anonymous and their data kept confidential (see section 4.3 Anonymity and Confidentiality).

4.2 Description and Management of Risks

Describe what is known about the risks (harm) of participating in the proposed research and any possible vulnerability that needs to be considered. Indicate how you will address these risks. Include literature related to the risks and the management of risks if relevant. Include any information about discomfort or incapacity that the participants are likely to experience as a result of the research.

Risks to participants

- Participants are encouraged to only disclose information that they feel comfortable sharing, however the possibility remains that while reflecting upon and sharing their lived experiences with ayahuasca, some participants may experience stress, discomfort, and/or emotional reactions.
- The use of ayahuasca is illegal in Canada, therefore if participants' confidentiality is compromised, they could possibly face legal consequences. However, the likelihood of a persecution risk is quite low, given that no legal trials have occurred in Canada regarding the use or administration of ayahuasca.
- Although pseudonyms are used to protect participants' identities, there is a risk that relatives or acquaintances could re-identify them based on direct quotes, personal anecdotes, or personal descriptions shared in their interviews.

Management of risks

- To minimize the possible stated risks, the student researcher will provide a safe, non-judgmental environment for participants to share their stories and experiences without coercion. Appropriate steps will be taken to discontinue interviews if the participant becomes triggered or distressed in any way. Participants will be fully informed that they can take breaks during the interview, ask to reschedule the interview, and ask that the audio recording device be paused or turned off. If the student researcher observes signs of distress, participants will be asked if they feel they would still like to continue. If a break is requested, the participant will be asked if they wish to obtain support from the reference list provided, to continue the interview thereafter, reschedule it for a near future date, or if they would like to withdraw from the study. Participants who wish to withdraw from the study will be asked if they would like a referral for further assistance.
- A list of counseling resources, as part of the informed consent (Appendices G and H), will also be provided to all participants.
- All data will be kept confidential and participants will not be identified by name in any publications of the research. Participants will be asked to adopt a pseudonym throughout the duration of the study. These false names will be used during interviews, in transcriptions, and whenever quotes are included in publications. Participants will be informed of the aforementioned risks and management of risks before consenting to partake in the study. They will have the opportunity to remove or alter any potentially identifying information they choose to decrease the likelihood of people re-identifying them. They can also withdraw from the study and have their data removed up to one month after their interview if they choose, without negative consequences.
- Participants' real names will be written on a few documents: the Initial Participant Contact Email,



Phone Scripts, and Informed Consent Form (Appendices D-H). All email correspondence will be deleted. The printed forms (Phone Scripts and Informed Consent Forms) will be stored in a locked storage closet at the student researcher's place of residence, and only accessible to her.

4.3 Anonymity and Confidentiality

If you indicate that you are collecting anonymous or anonymized data online, how you are ensuring the anonymity of participants?

N/A

Are you collecting information or data that can reasonably be expected to identify participants? If so, how will you protect participants' confidentiality both during (collection and use of information) and after (dissemination of results) the research study?

- Potential participants will be asked to provide their contact information via email, in response to the Initial Participant Contact Script (Appendix D). The student researcher will transfer their contact information from email onto the Phone Scripts (Appendices E and F); all email correspondence will then be deleted. The Phone Scripts and signed Informed Consent Forms (Appendices E-H) will contain identifying information, thus, to protect this information, these documents will be stored in a locked storage container at the student researcher's place of residence during the study and for five years after its completion.
- Pseudonyms will be used throughout the study (in interviews, transcriptions, and quotes) to protect participants' identities. Participants' real names will never appear in any written or verbal dissemination of the study.
- Audio recordings will be transcribed in privacy at the student research assistant's residence rather than in a public setting, in order to reduce the risk of someone outside of the study possibly recognizing participants. Electronic audio recordings and transcriptions will be stored in encrypted computerized files and Word documents during and after five years of completion of the study. Printed transcriptions will be securely stored in a locked storage container in the student researcher's place of residence. Only the research team will have access to the audio recordings and transcriptions.

How will you ensure that participants cannot be identified or re-identified through demographic data and/or direct quotes and/or participant descriptions (e.g. job description) in any dissemination of your research (including thesis or dissertation)?

- Participants will be asked to adopt pseudonyms throughout the study to protect their identities, however there remains a chance that relatives, colleagues, and/or other acquaintances could possibly re-identify them based on direct quotes, personal anecdotes, or personal descriptions shared in their interview. Participants will be notified of this potential risk, outlined in the Informed Consent Form (Appendices G and H) and will have the opportunity to remove or alter any potentially identifying information they choose.

What, if any, limits to confidentiality are considerations in your research, what is your rationale for including them, and how will they be communicated to participants?



- The Informed Consent Form (Appendices G and H) outlines the limits of confidentiality. Participants will be notified before consenting to their participation that personal information will be held confidential unless: 1) they disclose that a child or vulnerable adult is at risk of abuse or neglect and is in need of protection; 2) if they or another person is at clear risk of imminent harm; and 3) if the student researcher is required to comply with a legal order such as a court subpoena.

4.4 Benefits

The benefits to participation include:

- Participants may experience validation, satisfaction and/or other positive emotions from reflecting on and sharing how their ayahuasca experiences have been beneficial or therapeutic.
- Participants may develop new insights about these experiences.
- Validation interviews (Appendix L) will provide participants with an opportunity to reflect on how they may have benefited from participating in the research.
- Participants may feel empowered as equal co-creators in research and of scientific knowledge. The student researcher will notify each participant that this study is *our* research; the study involves a collaborative approach between each participant and the research team throughout data collection, analysis and validation of findings. Participants are viewed as the experts in their lived experiences with ayahuasca, thus their responses are highly valued in co-creating scientific knowledge regarding ayahuasca's therapeutic potential. They might feel empowered knowing that their responses will help Western mental health professionals understand therapeutic benefits and risks of ayahuasca, and will help develop evidence-based guidelines for professionals to support clients who have used, or planning to use, ayahuasca for healing purposes.
- This study may also benefit counsellors and other mental health professionals who may work with clients who have used ayahuasca or are interested in ayahuasca-assisted therapies in future. With evidence-based guidelines, mental health professionals could better support ayahuasca clients before and after ceremony to help maximize therapeutic potential and minimize risks.
- This study could provide valuable information to the field of psychology, mental health, and other related fields within the health care industry regarding the use of ayahuasca-assisted therapies. The findings of this research may be applied to ayahuasca-assisted therapies, treatment plans, and/or ways of conceptualizing of working with clients who have used, or planning to use ayahuasca therapeutically.

4.5 Peer Review

N/A

5. PARTICIPANT INFORMATION AND CONSENT PROCESS

5.1 Sites for Study

Interviews will occur in a private room at Adler University or another private, mutually agreed upon location (e.g., a private room at a library or in a community centre).

5.2 Time Requested of Participants

How much time will each participant be asked to dedicate to the research study?

- About 1.5 – 3 hours over the course of a year. Specifically there will be one 1 – 2 hour(s) in-person, audio-recorded, confidential interview to describe their experiences, and one 30 – 60



minutes follow-up, confidential phone interview to discuss results.

5.3 Reimbursements and Incentives for Participation

N/A

5.4 Assessment of Capacity

A. Initial assessment of capacity for the purposes of informed consent

Will every participant have the capacity to give fully informed consent on his/her own behalf?

Yes

Rationale:

Participants are 19 years of age and over and live as autonomous adults within their family, workplace, and communities. They are reasonably expected to have the competence to understand the research (based on the recruitment and informed consent materials) and to voluntarily agree to participate. Initial contact, including discussion of inclusion and exclusion criteria as well as the process of informed consent, will provide sufficient understanding of capacity. Before the Informed Consent Form (Appendices G and H) is signed, the student researcher will review the form with participants then ask them to describe their understanding of the potential risks and benefits of this research. Their capacity to consent is determined by their ability to demonstrate this understanding and explain what they are consenting to.

B. Ongoing assessment of capacity

How will capacity be assessed throughout the research if the participants' involvement goes beyond a single interview or completion of a questionnaire?

- Before commencing the Participation Validation Check Interview (Appendix L), the student researcher will assess the participants' capacity to provide informed consent for continued participation by reviewing the Informed Consent Form (Appendices G and H). Once again, the participant must demonstrate their understanding of what they are consenting to.

5.5 Explanation of Consent Forms to Potential Participants

How will the Informed Consent Form be reviewed?

- The Informed Consent Form (Appendices G and H) will be sent via e-mail to potential participants following a telephone screening with the student researcher utilizing the Phone Scripts for Potential Participants (Appendices E and F). Once potential participants have received the informed consent form, they will have one week to review the informed consent form and contact the student researcher to ask any questions and/or to confirm their interest in participating in the study. If the student researcher has not been contacted within a week, she will contact the potential participants by phone or e-mail as discussed during the telephone screening.
- The Informed Consent Form (Appendices G and H) will also be discussed thoroughly in



person with potential participants at their initial interview meeting. Potential participants will have the opportunity to ask the student researcher any further questions. Once all inquiries have been addressed to the potential participants' satisfaction, potential participants may choose to sign the informed consent form, thereby providing formal consent to participate in the study.

- Informed consent will be also be reviewed at the start of the validation interviews.

How much time will the participants have to review the Informed Consent Form?

- Potential participants will have at least one week to review the informed consent form on their own before agreeing to arrange an initial interview appointment with the student researcher. At the initial interview, the potential participant will also have approximately 5 – 10 minutes to review the form with the student researcher and ask any questions they may have regarding the research purpose, risks and benefits, and participation process. Lastly, before the validation interviews begin, another 5 – 10 minutes approximately will be devoted to reviewing informed consent.

5.6 Explanation of Assent Forms to Potential Participants

Will you be using Assent Forms in your research?

No

If yes, explain your process for presenting and completing the Assent Form, including who will be involved in each step: general process for assent: N/A

5.7 Assistance with Consent

N/A

5.8 Translation

Will any of your recruitment, consent or other documents be available in a language other than English?

No

Will interactions with participants be taking place in any language other than English?

No

If Yes to either or both questions, provide information regarding the translation process. N/A

5.9 Withdrawal of Data

How will participants be informed of their right to request their data be withdrawn from the study and how will you remove the data?



Participants will be notified of their right to withdraw themselves from the study, should they choose to at any time. They will be given the option to withdraw from the study and have their data deleted if they become distressed during the interview process. They will also have the right to refrain from answering questions of choice but still continue with the interview if they choose to. Their data can also be withdrawn up to one month after their initial interview.

5.10 Summary of Results to Participants

How will you provide a summary of results to participants – including strategies for maintaining anonymity if that has been included in informed consent process?

- During the process of informed consent, participants will be provided with the opportunity to choose whether or not they would like to receive a copy of the findings from the research study via email.

6. SECURITY OF INFORMATION AND DATA

6.1 Access to Information or Data by Persons within Adler University – Vancouver Campus

During data collection and analysis, who will have access to information collected or data related to your research study?

- The research team will have access to encrypted audio taped interviews, transcribed materials, and analytic journals (any paper trails of stages involved in analysis to systematically reveal the analytic decisions and interpretation of the data).

How will all of those who have access to that information or data be made aware of their responsibilities to protect confidentiality?

- The responsibility to protect data confidentiality has been discussed and will continue to be discussed between the student researcher and research team for the duration of the study and for five years after its completion. In addition, the entire research team including Dr. Thomas and the student researcher assistant will sign the Research Team Confidentiality Agreement Form.

Please describe in detail what information or data will be transferred among researchers (including research team and transcription services etc.) during data collection and analysis?

- Audio taped interviews will be immediately transferred into an encrypted folder in the student researcher's, password protected computer. This encrypted folder will be shared with the student research assistant to transcribe the interviews into encrypted Word documents. The dissertation chair and committee members will have access to these encrypted files if they



choose to review them before analysis. Encrypted files will be exchanged between the research team via the Internet using the encrypted file transfer software, Workspace 2.0, controlled by UBC's secure and encrypted IT system..

- All transcribed material and analytic journals will be shared amongst the student researcher and student research assistant during data analysis to conduct an external audit. Once again, other members of the research team will have access to these documents if they wish to review the analytic process.

How will you maintain confidentiality concerning participants' identities and how will you communicate this to participants?

- Potential participants will be asked to provide their contact information via email, in response to the Initial Participant Contact Script (Appendix D). The student researcher will transfer their contact information from email onto the Phone Scripts (Appendices E and F); all email correspondence will then be deleted. The Phone Scripts and signed Informed Consent Forms (Appendices E - H) will contain identifying information, thus, to protect this information, these documents will be stored in a locked storage container at the student researcher's place of residence during the study and for five years after its completion.
- Pseudonyms will be used throughout the study (in interviews, transcriptions, and quotes) to protect participants' identities. Participants' real names will never appear in any written or verbal dissemination of the study.
- Audio recordings will be immediately transferred into an encrypted folder in the student researcher's, password protected computer. This encrypted folder will be sent to the student researcher assistant for transcription into encrypted Word documents; specifically, the encrypted folder will be sent over the Internet using the encrypted file transfer software, Workspace 2.0. Audio recordings will be transcribed in privacy at the student research assistant's residence rather than in a public setting, in order to reduce the risk of someone outside of the study possibly recognizing participants. Electronic audio recordings and transcriptions will be stored in encrypted computerized files and Word documents during and after five years of completion of the study. Printed transcriptions will be securely stored in a locked storage container in the student researcher's place of residence. Only the research team will have access to the audio recordings and transcriptions.
- The Informed Consent Form (Appendices G and H) outlines the aforementioned process of providing and maintaining confidentiality to potential participants before giving consent if they choose.

6.2 Access to Information or Data by Persons Outside of Adler University – Vancouver Campus

Will any information collected during or raw data relating to your research study be available to persons or agencies outside of Adler University-Vancouver Campus?

- Yes

If yes, describe in detail what information or data will be available, how it will be transferred and stored, how participants' identities will be protected, and how you are communicating this to participants.



- Dr. Gerald Thomas, a dissertation committee member, is affiliated with UBC. As a member of the research team, he will have access to encrypted audio files and transcribed materials to review during the analytic process, if requested. Requested encrypted files will be exchanged over the Internet using the encryption software, Workspace 2.0. Raw data relating to this study will not be available to his colleagues or anyone else at UBC or outside of Adler University.

6.3 Post- Study Storage and Security of Data

During your research, how will data be secured (original and back-ups)? Please include information on storage and deletion of participant's contact information, where applicable, as well as data collected during research.

- During the research study, electronic data (including audio recordings and transcriptions) will be stored in an encrypted computerized folder (in the student researcher's computer). A back-up of the encrypted folder will also be stored in a password protected USB, which will be stored in a locked storage container at the student researcher's place of residence at all times.
- All paper copies of forms and documents (including signed consent forms, phone scripts, transcriptions, interview notes, analytic journals, and any materials with participant-identifying information) will stored in the same locked storage container at all times, unless being used by the research team.

After research (collection, use, dissemination) has been completed, how will different forms of data (original and back-ups) be stored and how will you maintain storage security for 5 years? If data will be kept on the Web, what precautions have been taken to keep it secure?

- All forms of data (electronic and paper copies) will be securely stored in a locked storage container at the student researcher's place of residence for five years after research completion.
- After five years of storing the data, all electronic files will be permanently erased from encrypted computerized folders and the back-up password protected USB drive. The student researcher will also shred all hard copies of forms and documents.

6.4 Future Use of Data

N/A.

7. APPLICATION SUBMISSION**7.2 Appendices**

Appendices must be included for all verbal or written communication with external institutions or agencies (including collaborators), key informants or other recruitment sources, potential participants and participants. They must be included in the chronological order they will be used during your research. The labelling (Appendix A; Appendix B; and so on) must match the labelling in your Application.



Appendices include, but are not limited to:

Initial contact with external institutions or agencies.

- Letters of support from collaborating or supporting agencies or institutions.
- Recruitment materials, including verbal scripts, e-mails, internet messages, etc.
- Scripts or e-mails for initial contact with participants, including acceptance or refusal
- Informed Consent Forms or verbal scripts.
- Assent Forms.
- Data collection instruments, guides, questionnaires, etc., including preliminary scripts.
- For on-line research, information concerning the software platform you will be using (e.g. HostedInCanada; Fluid Surveys) including information concerning issues such as privacy, future storage of data, randomization of participants. See FAQs for all questions concerning using on-line data collection methods.
- Deception Forms and any scripts for debriefing.
- Peer review reports if required.
- Confidentiality agreements for research team members and/or staff.
- E-mails from translation research assistants including qualifications and availability.



Insert all Appendices below in the chronological order they will be used during your research:

Appendix A: Recruitment Inquiry Letter

Appendix B: Recruitment Poster for Ayahuasca Users

Appendix C: Recruitment Poster for Ayahuasca Ceremony Leaders

Appendix D: Initial Participant Contact Email

Appendix E: Phone Script for Potential Ayahuasca User Participants

Appendix F: Phone Script for Potential Ayahuasca Ceremony Leader Participants

Appendix G: Informed Consent Form for Ayahuasca User Participants

Appendix H: Informed Consent Form for Ayahuasca Ceremony Leader Participants

Appendix I: Interview Guide for Ayahuasca Users

Appendix J: Interview Guide for Ayahuasca Ceremony Leaders

Appendix K: Participant Validation Check Interview

**Appendix A: Recruitment Inquiry Letter**

Dear (member of ayahuasca community),

I am looking for participants for a student's study. Her name is Melanie Oliveira. She is a Doctor of Psychology in Clinical Psychology (Psy.D.) student at Adler University. She designed a study as part of her degree. This study looks at how ayahuasca could be healing and how pre- and post-ceremony factors affect outcomes. The results will help mental health clinicians learn about the benefits and risks of this tea. They will also help develop guidelines for clinicians to support clients using this medicine. This study is supervised by Dr. Anna Khaylis, Dr. Michael Mandrusiak and myself.

Participants must be adults (19 years or older) and participated in five or more ceremonies. They will be asked about their experiences using this tea and what they did before and after ceremony. Ceremony leaders are also needed in this study. They must have led at least twenty ceremonies. They will be asked about their knowledge of the tea and experiences leading ceremonies.

The first interview will be in-person, audio-taped, and 1 – 2 hours. Results will be reviewed in a follow-up 30 – 60 minute phone interview. All data is confidential and participants will not be identified by name. A summary of the results will be emailed to each participant if they choose.

Attached to this email are two recruitment posters, one for ayahuasca users and the other for ceremony leaders. These posters can be shared with anyone of interest. Please feel free to contact me via email to address any concerns or comments you may have.

Thank you very much for your time and consideration.

Sincerely,

Dr. Gerald Thomas

**Appendix B: Recruitment Poster for Ayahuasca Users**

A Research Study On

The Therapeutic Effects of Ayahuasca and How Preparation and Integration Practices Influence the Quality of Therapeutic Outcomes

Melanie Oliveira is a Doctor of Psychology student at Adler University. She designed a study as part of her degree. This study looks at how ayahuasca is healing and how pre- and post-ceremony practices influence outcomes. Her supervisors are Dr. Anna Khaylis and Dr. Gerald Thomas.

You are invited to participate if you:

- Are a Canadian resident;
- Speak English;
- Are 19 years or older;
- Been to 5 or more ayahuasca ceremonies;
- Had different outcomes (i.e., some that were significant or deeply healing, while others were not);
- Want to speak about your experience using this tea;
- Want to speak about the practices used before and after ceremony, to prepare for and integrate the experience;
- Can complete up to 3 hours of interviews within a one-year time frame;
- Live in the Lower Mainland or able to visit this area for one interview.

Participation in the study will involve:

- About 1.5 – 3 hours of interviews:
 - One 1 – 2 hour(s), in-person, audio-recorded interview to share your experience
 - One 30 – 60 minutes, follow-up phone interview to discuss results.

Participants' responses will be used to help:

- Mental health clinicians understand the effects of this tea
- Make guidelines for clinicians to support clients using this tea.

A false name will be used in the study to protect your identity.
Results of the study will be shared with participants if they choose.

Please email Melanie to learn more or participate: -----.

**Appendix C: Recruitment Poster for Ayahuasca Ceremony Leaders**

A Research Study On

The Therapeutic Effects of Ayahuasca and How Preparation and Integration Practices Influence the Quality of Therapeutic Outcomes

Melanie Oliveira is a Doctor of Psychology student at Adler University. She designed a study as part of her degree. This study looks at how ayahuasca is healing and how pre- and post-ceremony practices influence outcomes. Her supervisors are Dr. Anna Khaylis and Dr. Gerald Thomas.

You are invited to participate if you:

- Speak English
- Are 19 years or older;
- Received qualified training as a shaman, neo-shaman, or curandero in the ritual or ceremonial use of ayahuasca;
- Led 20 or more ceremonies after completing training;
- Want to speak about your experience using this tea with clients;
- Want to discuss practices used with clients before and after ceremonies;
- Can complete up to 3 hours of interviews within a one year time frame;
- Live in the Lower Mainland or capable of visiting this area for one interview.

Participation in the study will involve:

- About 1.5 – 3 hours for interviews:
 - One 1 – 2 hour(s), in-person, audio-recorded interview to share your experience
 - One 30 – 60 minutes, follow-up phone interview to discuss results.

Participants' responses will be used to help:

- Mental health clinicians understand the effects of this tea;
- Make guidelines for clinicians to support clients using this tea.

A false name will be used in the study to protect your identity.
Results of the study will be shared with participants if they choose.

Please email Melanie to learn more or participate:

-----:

Appendix D: Initial Participant Contact Email

If an individual contacts the student researcher via email expressing interest in participating in the study, as an ayahuasca user or ceremony leader, the student researcher will respond using the following script:

Hello (potential participant's name):

This is Melanie Oliveira, the doctoral student researcher from Adler University. Thank you very much for your interest in my study regarding ayahuasca. I would like to arrange a brief phone interview to determine if you are eligible to participate in this study. I will also discuss more details of the study with you at that time. Please let me know a phone number and available times to contact you, and if leaving a voice message is alright.

Thank you again for your interest. I look forward to speaking with you. Have a lovely morning/afternoon/evening.

Sincerely,

Melanie Oliveira
Psy.D. in Clinical Psychology, Adler University

If participant slots have already been filled in the study, I will inform the individual of the waitlist using the following script:

Hello (potential participant's name):

This is Melanie Oliveira, the doctoral student researcher from Adler University. Thank you very much for your interest in my study regarding ayahuasca. At this present time, all participant slots in the study have been filled. However, if you meet participation criteria and wish to be placed on a waitlist, we could arrange that.

Please let me know if you remain interested. If so, we can schedule a brief phone interview to determine if you are eligible to participate in this study. I will also discuss more details of the study with you at that time. Please inform me of a phone number, available times to contact you, and if leaving a voice message is alright.

Thank you again for your interest. I look forward to speaking with you. Have a lovely morning/afternoon/evening.

Sincerely,

Melanie Oliveira
Psy.D. in Clinical Psychology, Adler University

Appendix E: Phone Script for Potential Ayahuasca User Participants

Hello (potential participant's name). This is Melanie Oliveira, the doctoral student researcher from Adler University. Thank you very much for your interest in my study regarding ayahuasca and taking the time to speak with me today.

Before we get started I would like to ask you a few short questions to ensure that you meet the requirements for this study. (*Participants that reply "yes" to the following questions are eligible.*)

1. Are you a Canadian resident?
2. Do you speak English?
3. Are you 19 years or older?
4. How many ayahuasca ceremonies have you participated in? (yes = 5 or more)
5. Have you had variable ayahuasca outcomes, for example, some experiences where deep, sustained healing occurred and others that were less significant, therapeutic or had minimal effects?
6. Are you willing to speak about your personal experiences using ayahuasca, including perceived benefits and risks?
7. Can you recall and are willing to describe the rituals, practices, or procedures used before and after ceremonies to prepare you for, and integrate the experience?
8. Are you comfortable completing up to 3 hours of interviews within a one year time frame?
9. Do you live in the Lower Mainland or capable of travelling to this area once for an in-person interview?
10. Do you have a medical history of psychosis? Are you currently experiencing symptoms of psychosis?
11. A medical history of suicidality? Are you currently suicidal?
(*If the individual discloses active psychosis or suicidality, the student researcher will provide him/her/they with the Crisis Centre Hotline and a list of other resources from the Informed Consent Form, Appendices G and H.*)

Participant is NOT eligible:

Thank you very much for your time and willingness to participate in this study. Unfortunately, I can only invite participants who meet all the set criteria for this study. I truly appreciate your time and interest. (*The student researcher will provide him/her/they with the list of resources outlined in the Informed Consent Form, Appendices G and H.*)

Participant IS eligible:

Thank you for answering my questions. Based on your responses, you are eligible for this study, so now I would like to take a few minutes to review the purpose of my research and what is required from participants. This information will help you decide if you would like to participate in the study. Please feel free to ask questions at any time.

The purpose of this study is to investigate the perceived therapeutic effects of ayahuasca, and how individuals can best prepare for and integrate their experience. Ayahuasca users and



ceremony leaders will be invited to share their personal and professional experiences with ayahuasca. Their responses will be used to help Western mental health professionals understand the therapeutic potentials of ayahuasca, and to help develop guidelines for professionals to support clients in ayahuasca-assisted therapy.

The study involves one in-person, audio-recorded interview that lasts approximately 1-2 hours. You will be asked to share your personal experiences using ayahuasca. You can talk about how some experiences have been helpful or therapeutic, and other experiences that were less significant or unbeneficial. You will be asked to discuss the rituals, practices or procedures used before and after your ayahuasca ceremonies, and which ones you've found to be most helpful to having therapeutic or beneficial outcomes. You will be asked to adopt a false name throughout your interview to protect your identity. The audio-recording will be stored in an encrypted computerized folder as well.

Once your responses have been analyzed, I will contact you to arrange a phone interview to discuss overall themes found in your responses and for you to verify if they accurately reflect your experience. This interview will last approximately 30 – 60 minutes.

Your participation in this study is completely voluntary and your real name will never appear in any publications of this research, only the pseudonym if short quotes are used.

Lastly, once the research is complete, a summary of the results can be shared with you if you choose. Do you have any questions?

If you are still interested in participating, I will email you a copy of the informed consent form to look over. Please contact me within one week to inform if you would or would not like to participate in this study. If I do not hear back from you within 7 days, may I contact you via phone or email to ask about your decision? Is it okay to leave a voicemail on the number you have provided?

If you decide to participate, we will schedule our initial interview, which can take place at my school, Adler University, or another confidential location that we decide on together. I will review the informed consent form with you in person and kindly ask you to sign it before audio-recording the interview.

Do you have any questions about the study at this point? Please feel free to e-mail me should you have any. Once again, thank you very much for your time and interest. I look forward to hearing from you soon.

Potential Participant's age:

email:

tel:

(Message ok:)

**Appendix F: Phone Script for Potential Ayahuasca Ceremony Leader Participants**

Hello (potential participant's name). This is Melanie Oliveira, the doctoral student researcher from Adler University. Thank you very much for your interest in my study regarding ayahuasca and taking the time to speak with me today.

Before we get started I would like to ask you a few short questions to ensure that you meet the requirements for this study. (*Participants that reply "yes" to the following questions are eligible.*)

1. Do you speak English?
2. Are you 19 years or older?
3. Have you received training as a shaman, neo-shaman, or curandero in the ritual or ceremonial use of ayahuasca?
4. How many ayahuasca ceremonies for clients have you facilitated?(20 or more =yes)
5. Are you willing to speak about your professional experience using ayahuasca with clients?
6. Are you willing to discuss the pre- and post-ceremony rituals or procedures used in your professional work?
7. Are you comfortable completing up to 3 hours of interviews within a one year time frame?
8. Do you live in the Lower Mainland or capable of travelling to this area once for an in-person interview?

Participant is NOT eligible:

Thank you very much for your time and willingness to participate in this study. Unfortunately, I can only invite participants who meet all the set criteria for this study. I truly appreciate your time and interest. (*The student researcher will provide him/her/they with the list of resources outlined in the Informed Consent Form, Appendices G and H.*)

Participant IS eligible:

Thank you for answering my questions. Based on your responses, you are eligible for this study, so now I would like to take a few minutes to review the purpose of my research and what is required from participants. This information will help you decide if you would like to participate in the study. Please feel free to ask questions at any time.

The purpose of this study is to investigate the perceived therapeutic effects of ayahuasca, and how individuals can best prepare for and integrate their experience. Ayahuasca users and ceremony leaders will be invited to share their personal and professional experiences with ayahuasca. Their responses will be used to help Western mental health professionals understand the therapeutic potentials of ayahuasca, and to help develop guidelines for professionals to support clients in ayahuasca-assisted therapy.

The study involves one in-person, audio-recorded interview that lasts approximately 1-2 hours. You will be asked to share your professional experience facilitating ayahuasca ceremonies with clients, including how the ritualized use of ayahuasca has been helpful or therapeutic for some clients, and less significant or minimally therapeutic for others. You will also be asked to



describe the pre- and post-ceremony rituals, practices or procedures used in your professional work, and how these and others best influence deep, sustained healing or beneficial outcomes. You will be asked to adopt a false name throughout your interview to protect your identity. The audio-recording will be stored in an encrypted computerized folder as well.

Once your responses have been analyzed, I will contact you to arrange a phone interview to discuss overall themes found in your responses and for you to verify if they accurately reflect your experience. This interview will last approximately 30 – 60 minutes.

Your participation in this study is completely voluntary and your real name will never appear in any publications of this research, only the pseudonym if short quotes are used.

Lastly, once the research is complete, a summary of the results will be shared with you if you choose. Do you have any questions?

If you are still interested in participating, I will email you a copy of the informed consent form to look over. Please contact me within one week to inform if you would or would not like to participate in this study. If I do not hear back from you within 7 days, may I contact you via phone or email to ask about your decision? Is it okay to leave a voicemail on the number you have provided?

If you decide to participate, we will schedule our initial interview, which can take place at my school, Adler University, or another confidential location that we decide on together. I will review the informed consent form with you in person and kindly ask you to sign it before audio-recording the interview.

Do you have any questions about the study at this point? Please feel free to e-mail me should you have any. Once again, thank you very much for your time and interest. I look forward to hearing from you soon.

Potential Participant's age:

email:

tel:

(Message ok:)

**Appendices G: Informed Consent Form for Ayahuasca User Participants****INFORMED CONSENT FORM****The Therapeutic Effects of Ayahuasca and How Preparation and Integration Practices Influence the Quality of Therapeutic Outcomes****The Researchers**

My name is Melanie Oliveira. I am doing this research as part of my doctoral degree in the Doctor of Psychology in Clinical Psychology (Psy.D.) Program at Adler University (Vancouver Campus).

If you have any questions about the research, you can contact me or my Advisor. Our contact information is below:

Student Researcher: Melanie Oliveira

E-mail: -----

Research Advisor: Dr. Anna Khaylis
Phone: 604-699-3544

Program: Psy. D.
E-mail: akhaylis@adler.edu

The research has been approved by the Adler University (Vancouver Campus) Research Ethics Board (REB).

This Research

The research focuses on: the effects of ayahuasca and how pre- and post-ceremony practices influence healing outcomes.

We are asking you to participate because you:

- Are a Canadian resident
- Speak English
- Are 19 years or older
- Been to 5 or more ayahuasca ceremonies
- Had different outcomes (i.e., some that were significant while others were not);
- Want to speak about your experiences using this tea
- Want to speak about the practices used before and after ceremonies
- Can complete up to 3 hours of interviews within a one-year time frame
- Live in the Lower Mainland or capable of visiting this area for one interview.

As part of our research, we are asking you to do the following:

- Talk about your experiences using this tea. You will talk about how some experiences have been healing or helpful, whereas other were less significant.
- Talk about the practices used before and after ceremonies.
- Share your thoughts regarding the benefits and risks of this tea.



- Discuss what you would recommend to mental health clinicians working with clients using this tea.

You will spend **1.5 – 3 hours for confidential interviews over 1 year**. These include:

- One 1 – 2 hour(s), in-person, audio-recorded interview to share your experiences
- One 30 – 60 minutes, follow-up phone interview to discuss results

We will meet somewhere private and quiet that works for both of us. For example, the interview can take place in a private room at Adler University, at a library or in a community centre, or another private place that works for us both.

The Research is Voluntary

You decide if you want to participate in this study. There is no problem if you say “no.” You can refrain from answering any questions. You may also withdraw from this study at any time for any reason. Your data can be withdrawn up to one month after your first interview.

The Research is Confidential

Information from this study that identifies you is kept confidential. You are referred to using a false name throughout the interview, in interview write-ups, and in the research report. Your real name or initials will never be used in any publications. Only the research team has access to the audio recordings and transcribed interviews. The research team includes the student researcher, research advisor, Dr. Michael Mandrusiak from Adler University, Dr. Gerald Thomas from the University of British Columbia, and a student research assistant from Adler University.

All electronic data (i.e. audio recordings and written interviews) will be stored for 5 years in an encrypted computer folder and a password protected USB drive. The USB drive will be placed in a locked storage container when not in use. Hard copies of the data will also be placed in the locked storage container for 5 years. The storage container will be securely stored at the student researcher’s home. After 5 years, hard copies of the data will be shredded. Electronic copies will be erased.

Limits to what is Confidential

Personal information collected is confidential unless:

- A) A child or adult is at risk of abuse/neglect and needs protection;
- B) You or someone is at risk of harm;
- C) I am required to follow legal orders (i.e., a court subpoena)

The Results of the Research

I will publish the results of the research in my dissertation. I may also write or speak about the research. Your name or any other information that might identify you will NOT be included in any writing or presentation.



Please indicate if you want a summary of the results, at the end of this form.

The Risks and Benefits

You might feel some stress when talking about your ayahuasca experiences. If you feel too distressed you can:

1. Decide not to answer a particular question.
2. Take a short break from answering questions.
3. Re-schedule your interview.
4. Withdraw from the research at any time.
5. Reach out to your support system.
6. Seek support from the resource referral list attached.

Although the research team keeps your identity and data confidential, there is a risk that someone reading published material about this study may re-identify you from direct quotes or personal anecdotes/descriptions in your interview. Thus, confidentiality is not guaranteed. A false name is used to reduce this risk. You may also remove/alter information that could identify you before results are shared.

Additionally, Dr. Gerald Thomas is a member of this research project. He works with ayahuasca communities in British Columbia. Since this community is small, he might be your colleague or acquaintance. If so, he might re-identify you from direct quotes or personal anecdotes. However, he is aware of his duty to protect your identity.

You may also learn something about yourself from answering the questions. You might gain new insights. You may feel positive emotions when talking about your healing experiences, as well.

You may also feel empowered by your involvement in this research. This is YOUR study, as well. You play a valuable role in providing data and validating the findings. You are the expert in your experiences with this tea. Thus, your responses are highly valuable in increasing scientific knowledge regarding the effects of this tea. Your answers will help make guidelines for clinicians to support clients using this tea.

If you have any concerns about your treatment as a participant, you may contact the Chair of the Research Ethics Board. Her contact information is below:

REB Chair: Debbie Clelland PhD (604) 699.3570
E-mail: dclelland@adler.edu

Consent for this Research:

- I understand my participation in this study is voluntary.
- I can refuse to answer any question.
- I can withdraw from this study at any time without consequence.
- I can ask that my information be removed up to one month after my interview.
- I know my in-person interview will be audio-recorded.



- I know quotes might be used.
- My name will NOT appear in any publications of this study.
- Any information that could identify me will be removed at my request.
- I know that the information I give is confidential. However, I understand that someone who knows me could possibly recognize my experience from direct quotes or personal anecdotes. Therefore, I know that confidentiality cannot be guaranteed.
- I know about the potential dual relationship with Dr. Thomas and still choose to participate in this study.
- I have not given up any legal rights concerning this research even though I have signed this form.
- I am giving my consent to participate in this study.
- I have received a copy of this Informed Consent signed by the Researcher.

Participant Signature

Date

Participant Name (Print)

Researcher Signature

Date

Researcher Name (Print)

I would like to receive a summary of the results of this research:

_____ Yes _____ e-mail address



1. Canadian Mental Health Association, BC Division

Five branches across the Lower Mainland including: Delta, North Vancouver, West Vancouver, Richmond, Simon Fraser (New Westminster), and Vancouver-Burnaby

Phone: 604-688-3234 or Toll-free (BC only): 1-800-555-8222

E-mail: info@cmha.bc.ca

Website: <http://www.cmha.bc.ca>

2. BC Association of Clinical Counsellors (BCACC)

Online directory of registered counsellors:

<http://bc-counsellors.force.com/CounsellorSearch>

3. CounsellingBC.com

Online directory of counsellors, psychologists, social workers, and therapists:

<http://counsellingbc.com/directory.html>

4. Crisis Centre Hotline: 1-800-784-2433

The Distress Phone Services provide confidential, free emotional support, 24 hours a day, 7 days a week, for people in distress.

**Appendices H: Informed Consent Form for Ayahuasca Ceremony Leader Participants****INFORMED CONSENT FORM****The Therapeutic Effects of Ayahuasca and How Preparation and Integration Practices Influence the Quality of Therapeutic Outcomes****The Researchers**

My name is Melanie Oliveira. I am doing this research as part of my doctoral degree in the Doctor of Psychology in Clinical Psychology (Psy.D.) Program at Adler University (Vancouver Campus).

If you have any questions about the research, you can contact me or my Advisor. Our contact information is below:

Student Researcher: Melanie Oliveira

E-mail: -----

Research Advisor: Dr. Anna Khaylis
Phone: 604-699-3544

Program: Psy. D.
E-mail: akhaylis@adler.edu

The research has been approved by the Adler University (Vancouver Campus) Research Ethics Board (REB).

This Research

The research focuses on: the effects of ayahuasca and how pre- and post-ceremony practices influence healing outcomes.

We are asking you to participate because you:

- Speak English
- Are 19 years or older
- Received qualified training as a shaman, neo-shaman or curandero in the ritual or ceremonial use of ayahuasca
- Led 20 or more ceremonies after completing training
- Want to speak about your experience using this tea with clients
- Want to discuss practices used with clients before and after your ceremonies
- Can complete up to 3 hours of interviews within a one year time frame
- Live in the Lower Mainland or capable of visiting this area for one interview

As part of our research, we are asking you to do the following:

- Talk about your experiences leading ayahuasca ceremonies with clients.
- Talk about the practices used with clients before and after ceremonies.
- Discuss the benefits and risks of this tea.
- Discuss what you would recommend to mental health clinicians working with clients using this tea.

You will spend **1.5 – 3 hours for confidential interviews over 1 year**. These include:

- One 1 – 2 hour(s), in-person, audio-recorded interview to share your experiences
- One 30 – 60 minutes, follow-up phone interview to discuss results

We will meet somewhere private and quiet that works for both of us. For example, the interview can take place in a private room at Adler University, at a library or in a community centre, or another private place that works for us both.

The Research is Voluntary

You decide if you want to participate in this study. There is no problem if you say “no.” You can refrain from answering any questions. You may also withdraw from this study at any time for any reason. Your data can be withdrawn at any time prior to data analysis.

The Research is Confidential

Information from this study that identifies you is kept confidential. You are referred to using a false name throughout the interview, in interview write-ups, and in the research report. Your real name or initials will never be used in any publications. Only the research team has access to the audio recordings and transcribed interviews. The research team includes the student researcher, research advisor, Dr. Michael Mandrusiak from Adler University, Dr. Gerald Thomas from the University of British Columbia, and a student research assistant from Adler University.

All electronic data (i.e. audio recordings and written interviews) will be stored for 5 years in an encrypted computer folder and a password protected USB drive. The USB drive will be placed in a locked storage container when not in use. Hard copies of the data will also be placed in the locked storage container for 5 years. The storage container will be securely stored at the student researcher’s home. After 5 years, hard copies of the data will be shredded. Electronic copies will be erased.

Limits to what is Confidential

Personal information collected is confidential unless:

- A) A child or adult is at risk of abuse/neglect and needs protection;
- B) You or someone is at risk of harm;
- C) I am required to follow legal orders (i.e., a court subpoena)

The Results of the Research

I will publish the results of the research in my dissertation. I may also write or speak about the research. Your name or any other information that might identify you will NOT be included in any writing or presentation.

Please indicate if you want a summary of the results, at the end of this form.

The Risks and Benefits

You might feel some stress when talking about your ayahuasca experiences. If you feel too distressed you can:

1. Decide not to answer a particular question.
2. Take a short break from answering questions.
3. Re-schedule your interview.
4. Withdraw from the research at any time.
5. Reach out to your support system.
6. Seek support from the resource referral list attached.

Although the research team keeps your identity and data confidential, there is a risk that someone reading published material about this study may re-identify you from direct quotes or personal anecdotes/descriptions in your interview. Thus, confidentiality is not guaranteed. A false name is used to reduce this risk. You may also remove/alter information that could identify you before results are shared.

Additionally, Dr. Gerald Thomas is a member of this research project. He works with ayahuasca communities in British Columbia. Since this community is small, he might be your colleague or acquaintance. If so, he might re-identify you from direct quotes or personal anecdotes. However, he is aware of his duty to protect your identity.

You may also learn something about yourself from answering the questions. You might gain new insights. You may feel positive emotions when talking about your healing experiences, as well.

You may also feel empowered by your involvement in this research. This is **YOUR** study, as well. You play a valuable role in providing data and validating the findings. You are the expert in your experiences with this tea. Thus, your responses are highly valuable in increasing scientific knowledge regarding the effects of this tea. Your answers will help make guidelines for clinicians to support clients using this tea.

If you have any concerns about your treatment as a participant, you may contact the Chair of the Research Ethics Board. Her contact information is below:

REB Chair: Debbie Clelland PhD (604) 699.3570
E-mail: dclelland@adler.edu

Consent for this Research:

- I understand my participation in this study is voluntary.
- I can refuse to answer any question.
- I can withdraw from this study at any time without consequence.
- I can ask that my information be removed up to one month after my interview.
- I know my in-person interview will be audio-recorded.
- I know quotes might be used.



- My name will NOT appear in any publications of this study.
- Any information that could identify me will be removed at my request.
- I know that the information I give is confidential. However, I understand that someone who knows me could possibly recognize my experience from direct quotes or personal anecdotes. Therefore, I know that confidentiality cannot be guaranteed.
- I know about the potential dual relationship with Dr. Thomas and still choose to participate in this study.
- I have not given up any legal rights concerning this research even though I have signed this form.
- I am giving my consent to participate in this study.
- I have received a copy of this Informed Consent signed by the Researcher.

Participant Signature

Date

Participant Name (Print)

Researcher Signature

Date

Researcher Name (Print)

I would like to receive a summary of the results of this research:

_____ Yes _____ e-mail address

Resource List:

1. Canadian Mental Health Association, BC Division

Five branches across the Lower Mainland including: Delta, North Vancouver, West Vancouver, Richmond, Simon Fraser (New Westminster), and Vancouver-Burnaby

Phone: 604-688-3234 or Toll-free (BC only): 1-800-555-8222

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Online directory of counsellors, psychologists, social workers, and therapists:

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4. Crisis Centre Hotline: 1-800-784-2433

The Distress Phone Services provide confidential, free emotional support, 24 hours a day, 7 days a week, for people in distress.

**Appendix I: Interview Guide for Ayahuasca Users**

Before beginning the audio recording, the student researcher will obtain Informed Consent (Appendix G) and engage in a brief check-in with participants:

“Thank you for meeting with me today. I truly appreciate your time and willingness to participate in our study. During this interview we will talk about your personal experiences attending ayahuasca ceremonies. At any time throughout this interview you may ask to take a break or reschedule. You can also refrain from answering any questions and can withdraw from the study at any point if you choose. To protect your identity, please choose a pseudonym or false name for the interview. Do you have any questions? Let us begin.”

Begin audio recording the interview:

- 1) “How many ayahuasca ceremonies have you attended in total?”
(Possible probe):
 - a. “Where did you attend these ceremonies?”
 - b. “What tradition do these ceremonies follow?”
- 2) “What are your main reason or reasons for attending ayahuasca ceremonies?”
(Possible probe):
 - a. “In what ways does ayahuasca help you address these concerns?”
- 3) What other methods have you tried to address these concerns?
(Possible probe):
 - a. “How did ayahuasca differ from those methods in addressing your concerns?”
- 4) “Describe your most significant or transformative ayahuasca experience.”
(Possible probes):
 - a. “Please describe the ceremony in more detail.”
 - b. “How did you prepare for this experience?”
 - c. “How much time was spent preparing for this experience?”
 - d. “How do you think preparation influenced the experience?”
 - e. “How did you process the experience after ceremony?”
 - f. “How you do think steps taken to process the experience influenced its significance?”
 - g. “What other factors do you think influenced this experience?”
- 5) “Please describe an experience of using ayahuasca that was not as significant or transformative as the one we just discussed.”
(Possible probes):
 - a. “Please describe the ceremony in more detail.”
 - b. “How did you prepare for this experience?”
 - c. “How much time was spent preparing for this experience?”
 - d. “How do you think preparation influenced the experience?”



- e. *“How did you process the experience after ceremony?”*
 - f. *“How you do think steps taken to process the experience influenced its significance?”*
 - g. *“What other factors do you think influenced this experience?”*
- 6) “How would you describe the overall impact of ayahuasca ceremonies in your life?”
- 7) “In what ways is the use of ayahuasca potentially beneficial for people engaging in ceremonies?”
- 8) “What are the potential risks of using ayahuasca for these purposes?”
(Possible probe):
- a. *“What do you think can be done to protect against these risks?”*
- 9) “What kind of preparations were recommended to you before you participated in an ayahuasca ceremony?”
(Possible probe):
- a. *“Who provided these recommendations?”*
- 10) “What kind of integration practices were recommended to you after you participated in an ayahuasca ceremony?”
(Possible probe):
- a. *“Who provided these recommendations?”*
- 11) “What would you recommend that mental health professionals do when working with clients before they attend an ayahuasca ceremony?”
- 12) “What would you recommend that mental health professionals do to assist clients with integration after they attend an ayahuasca ceremony?”
- 13) “Is there anything else you would like to share about your personal experiences with ayahuasca?”

Throughout the interview, I may use the following guiding questions and/or statements to provide more information and increase the depth of their response:

- “Please tell me more.”
 - “Tell me more about how that (experience, moment, time, realization, awareness, insight, etc.) was for you.”
 - “How was that (experience, event, awareness, etc.) significant for you?”
 - “What were your thoughts or feelings at that time?”
-



The following script will be used if a participant chooses to reschedule the interview or withdraw from the study:

(If rescheduling) “Would you like to reschedule our interview now? Or would you prefer to contact me via e-mail to reschedule? I would like to remind you of the resource referral list. Please refer to it if you need to speak to a professional about any distress you may be experiencing. Thank you for your time today.”

(If withdrawing) “I understand that you want to withdraw from the study. Would you like your data withdrawn from the study, as well? I would like to remind you of the resource referral list. Please refer to it if you need to speak to a professional about any distress you may be experiencing. Thank you for your time today.”

**Appendix J: Interview Guide for Ayahuasca Ceremony Leaders**

Before beginning the audio recording, the student researcher will obtain Informed Consent (Appendix H) and engage in a brief check-in with participants:

“Thank you for meeting with me today. I truly appreciate your time and willingness to participate. During our time together, we will talk about your professional experiences facilitating ayahuasca ceremonies. At any time throughout this interview you may ask to take a break or reschedule. You can also refrain from answering any questions and can withdraw from the study at any point if you choose. To protect your identity, please choose a pseudonym or false name for the interview. Do you have any questions? Let us begin.”

Begin audio recording the interview:

- 1) “Why do you facilitate ayahuasca ceremonies?”
- 2) “In what ways can ayahuasca be potentially therapeutic for clients?”
(Possible probes):
 - a. “Under which conditions or reasons would you recommend using ayahuasca?”
- 3) “What do you think are the potential risks for clients who use ayahuasca?”
(Possible probes):
 - a. “What is done to protect against these risks?”
 - b. “Under which conditions or reasons would you not recommend using ayahuasca?”
- 4) “How would you describe the overall impact of ayahuasca ceremonies in your client’s lives?”
- 5) “What preparations do you use with clients before they participate in an ayahuasca ceremony?”
(Possible probes):
 - a. “How might these preparations influence treatment outcomes?”
- 6) “What integration practices do you use with clients after participating in an ayahuasca ceremony?”
(Possible probes):
 - a. “How might these integration practices influence treatment outcomes?”
- 7) “What would you recommend to mental health professionals assisting clients before their ayahuasca ceremony?”
- 8) “What would you recommend to mental health professionals assisting clients after their ayahuasca ceremony?”



- 9) “Is there anything else you would like to share about your professional experience facilitating ayahuasca ceremonies and supporting clients?”

Throughout the interview, I may use the following guiding questions and/or statements to provide more information and increase the depth of their response:

- “Please tell me more.”
- “Tell me more about how that (experience, moment, time, realization, awareness, insight, etc.) was for you.”
- “How was that (experience, event, awareness, etc.) significant for you?”
- “What were your thoughts or feelings at that time?”

The following script will be used if a participant chooses to reschedule the interview or withdraw from the study:

(If rescheduling) “Would you like to reschedule our interview now? Or would you prefer to contact me via e-mail to reschedule? I would like to remind you of the resource referral list. Please refer to it if you need to speak to a professional about any distress you may be experiencing. Thank you for your time today.”

(If withdrawing) “I understand that you want to withdraw from the study. Would you like your data withdrawn from the study, as well? I would like to remind you of the resource referral list. Please refer to it if you need to speak to a professional about any distress you may be experiencing. Thank you for your time today.”

**Appendix K: Participant Validation Check Interview**

Hello (participant name).

In this final interview I will discuss the themes identified from your responses, then ask if the themes accurately represent your experiences and responses. I will also discuss the quotes I'd like to use from your interview, making sure they are accurate and protect your confidentiality before obtaining your permission for including them in the study. Before we begin, I would like to remind you of the Informed Consent Form (Appendix G and H) and give you the opportunity to review it once more and ask any questions.

Validation check questions:

1. Does this theme accurately reflect your experience/opinion/response?
2. Is there something from your response not captured in this theme?
3. Is there another theme that would better represent your experience/opinion/response?

Quote validation questions:

1. Is this quote accurate?
2. Is this quote too self-identifying? Do you think any parts may compromise your confidentiality?
3. Is there anything you do not want included?
4. May I include this quote in the study? Your pseudonym name will be identified with this quote.