

A PROPOSAL TO ANALYZE THE ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS (ELSI) OF PSILOCYBIN SERVICES

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INTRODUCTION

Dear Board Members,

At our next Board meeting, I wish to discuss my proposal for a future direction of our research. The following outline summarizes the proposal, which is a collaboration between Board members and a research initiative I founded at the Petrie-Flom Center at Harvard Law School. Because our meeting time is limited, I have attempted to anticipate potential questions regarding the proposal. Additional questions will undoubtedly arise, and I look forward to discussing them with you on August 25th.

Thank you for your consideration.

Best regards,
Mason Marks

ELSI RESEARCH PROPOSAL OUTLINE

1. Thanks to the efforts of the Research Subcommittee, the Oregon Psilocybin Advisory Board (the Board) produced an initial review of scientific literature on psilocybin therapy, the Rapid Evidence Review and Recommendations (the Rapid Review)
2. Having submitted the Rapid Review, the Board can now pursue a second round of research that addresses topics and viewpoints that had to be omitted from the Rapid Review due to time constraints.
3. Measure 109 requires the Board to make recommendations to the Oregon Health Authority (OHA) based on "available medical, psychological, and scientific studies, research, and other information relating to the safety and efficacy of psilocybin" The terms "research" and "other information" are broad and should be interpreted to encompass a variety of sources and research methods.
4. Measure 109 also requires the Board to "monitor and study federal laws, regulations and policies regarding psilocybin."
5. The proposed research project will draw from these varied sources of information, augment the Rapid Review, analyze the Ethical, Legal, and Social Implications (ELSI) of psilocybin services, and make recommendations to the OHA.
6. ELSI research is an internationally recognized approach that accommodates a variety of quantitative and qualitative methods. It was popularized in the context of genetics research and is now widely used in many disciplines including biology, medicine, ethics, law, policy, and the social sciences.

7. Potential sources of data include historical information on the Indigenous use of psilocybin, anthropology literature, religious scholarship, bioethics literature, medical and psychological literature from the mid-twentieth century, narrative descriptions of psilocybin use, public health data, legislative materials, and legal scholarship. The project will review and analyze existing research only. It will not collect data through surveys or other instruments.
8. The goal of the proposed research project is to produce a high-quality document (the ELSI Report) that will serve as a reference for the Board and the public, while providing guidance to the OHA and jurisdictions outside Oregon that choose to model legislation on Measure 109.
9. Production of the ELSI Report will be a partnership between members of the Board and an academic research initiative, the Project on Psychedelics Law and Regulation (POPLAR) at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.
10. Through the Board's work with POPLAR, OHA and the Board will sponsor the collaborative production of the ELSI Report, however, the OHA need provide no funding to support the project. Production of the ELSI Report will be conducted on a voluntary basis by members of the Board with support and participation from POPLAR faculty and staff.
11. POPLAR is funded entirely by a non-profit organization, the Saisei Foundation, and it receives no funds from industry. Mason Marks, who leads POPLAR, will not benefit financially from the production or publication of the ELSI Report.
12. Board members who make substantive contributions to the writing project will be listed as co-authors on the ELSI Report.
13. POPLAR and its Board member co-authors will aim to publish the ELSI Report in a highly ranked journal of science, medicine, law, or public policy. However, publication may require prior review by the OHA.
14. The partnership between the Board and POPLAR will extend only to production of the ELSI Report and will not extend to other business conducted by the Board or other POPLAR research, activities, or academic programs. However, there may be opportunities for Board members to participate in POPLAR events at the discretion of POPLAR leadership. The partnership between the Board and POPLAR will end upon publication of the ELSI Report, and any further collaborations will be discussed and approved separately.
15. The estimated time to completion of the ELSI Report is 4 – 6 months.
16. A non-exhaustive list of potential questions to be addressed by the ELSI Report includes the following:
 - a. How does psilocybin affect individuals, families, and communities?
 - b. How does psilocybin affect interpersonal relationships and social functioning?
 - c. How do different cultures and communities view psilocybin and how have their attitudes changed over time?
 - d. What accounts for the social stigma associated with psilocybin and how might it be addressed?
 - e. How do individuals who have received psilocybin describe their experiences in their own words?
 - f. What rituals have communities developed around psilocybin consumption?
 - g. How do communities who consume psilocybin describe their relationship with the substance and their rituals surrounding its use?

- h. How has psilocybin prohibition affected marginalized communities and how might the Oregon Model of psilocybin services affect them?
- i. How do different psychological instruments measure the experiences of people who use psilocybin?
- j. What spiritual and religious benefits do people report after consuming psilocybin?
- k. How has psilocybin prohibition impacted mental health research and the development of new psychiatric therapies?
- l. How does the availability of psilocybin services impact public health?
- m. How might psilocybin services affect rates of addiction, drug overdose, and suicide?
- n. Which federal laws affect the provision of psilocybin services?
- o. How have states and the federal government cooperated to regulate substances and how might they collaborate in the future?
- p. How have different cities, states, and countries approached psilocybin regulation, how has that regulation affected their populations, and how might it inform the implementation of Measure 109?