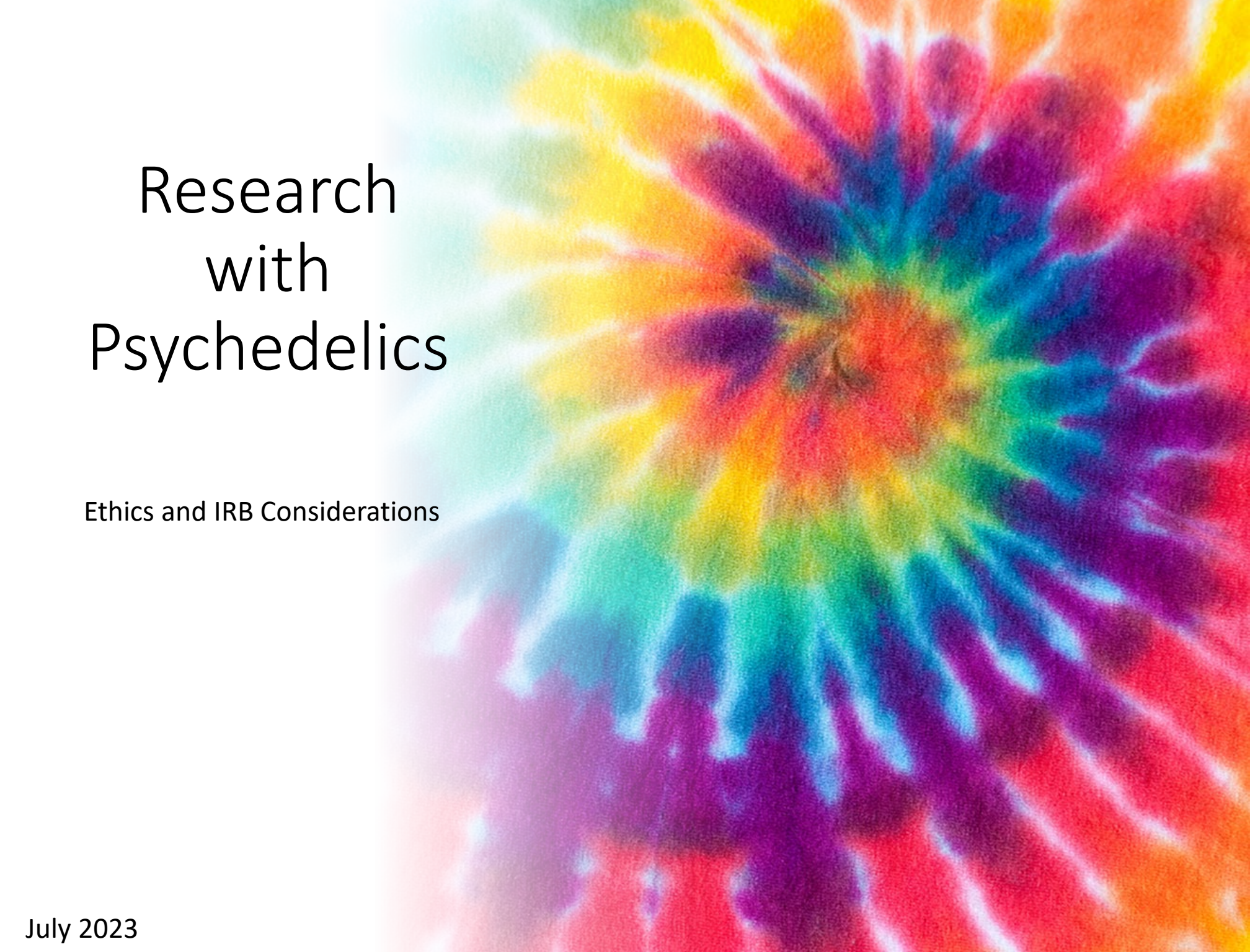
Research with Psychedelics

Ethics and IRB Considerations



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What are psychedelic drugs?

- A group of substances that change or enhance sensory perceptions, thought processes, and energy levels
- Sometimes called hallucinogens
- Schedule I Controlled Substances/No currently accepted medical use in the U.S.
- “Classic” psychedelics: LSD and psilocybin
- “Empathogens” – MDMA (ecstasy)

Brief Timeline

- LSD synthesized by Albert Hofmann in 1938
- Psychedelic research was popular in the 1950's
- Early 1960's The FDA designated LSD as an experimental agent
- Late 1960's LSD increasingly became viewed as a drug of abuse and outlawed in 1968
- 1990's renewed interest in potential therapeutic benefits
- 2000 – Johns Hopkins researchers obtain regulatory approval to resume psychedelic research
- June 2023 FDA issues draft guidance for psychedelic research

Some areas of study using psychedelics:

- Smoking cessation
- Major depression disorder
- Alzheimer's Disease (examining impact on depression in MCI and early dementia)
- Anorexia Nervosa
- Cancer-related anxiety and depression
- Alcohol dependence
- PTSD

IRB Considerations

- Careful screening
  - Exclude those with cardiovascular risk
  - Exclude those at risk for psychosis
  - Exclude contraindicated medications
- Careful preparation
  - Minimum 6-8 hours of rapport building
  - Unstructured counseling for patients
- Close monitoring during acute effects
  - Sessions typically last 6-8 hours
  - Non-directive, non-judgmental presence
- Aftercare / integration
  - Days and weeks after drug administration
  - Unstructured counseling for patients

Johnson et al., *J Psychopharmacol* 2008; 22(6):603-620

IRB Considerations

- Respect for Persons
  - Informed consent challenges
  - Vulnerability given society hype
  - Vulnerability during acute drug effects
- Beneficence
  - Are study teams adequately trained?
  - Are risks adequately understood by study team AND HRP staff?
- Justice
  - Are SOC/TAU enough?
  - Is the disease burden currently well-managed?
  - Is there adequate representation in the current literature?

Frederick S. Barrett, Ph.D., Johns Hopkins University School of Medicine, 2023 AAHRPP Conference

SOC = Standard of Care; TAU = Treatment as Usual

Steps for the Investigator

1) **Obtain IRB Approval**
   a) Review and approve using usual criteria for approval
   b) Approve with contingencies pending approval from additional agencies.

2) **Submit to the Research Advisory Panel (RAP) of California** for review and approval (https://oag.ca.gov/research/guide)
   a) Required by CA law for studies using Schedule I and Schedule II Controlled Substances as the main study drug
   b) RAP evaluates the scientific validity of each proposed project
   c) May reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of California subjects to the risk of research
   d) Researchers should obtain IRB and FDA approval of their study BEFORE submitting the study for review by the Research Advisory Panel of California.

3) **Submit a Form 225 to the DEA to obtain DEA approval** (https://deadiversion.usdoj.gov/)
   a) The study must comply with Drug Enforcement Administration (DEA) regulations for research, manufacturing, handling, storage
   b) DEA authorization is required to conduct each specific protocol

Resources

FDA Draft Guidance: Psychedelic Drugs: Considerations for Clinical Investigations, June 2023
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/psychedelic-drugs-considerations-clinical-investigations

U.S. Department of Justice Drug Enforcement Administration, Diversion Control Division
https://www.deadiversion.usdoj.gov/index.html

State of California Department of Justice, Research Advisory Panel
https://oag.ca.gov/research

USC Environmental Health & Safety, DEA Registration and Renewal
https://ehs.usc.edu/research/cspc/dea/#schedule4

USC HRPP – California Research Laws
https://hrpp.usc.edu/policies/california-research-laws/