Coalition for Medical Marijuana Research and Education

Medical Marijuana Research and Education Plan

(Approved by the Medical Marijuana Research and Education Board on October 30, 2017)

Objective 1: Research

Identify and prioritize the research eligible to be conducted through the Coalition to develop a comprehensive evidence base on the short- and long-term health effects of marijuana for medical use, addressing the key gaps in the evidence base. All research conducted through the Coalition must be in compliance with the U.S. Drug Enforcement Administration (DEA) and the U.S. Food and Drug Administration (FDA) policies and regulations. Research conducted will, in addition, be approved by relevant Institutional Review Board/Institutional Animal Care and Use Committee (IRB/IACUC).

Prioritized research streams and objectives may include, but shall not be limited to:

1a. Observational/Survey Research:

- Use observational research strategies to evaluate past history and current medical marijuana use, indication for use, bioavailability, potential beneficial and harmful health effects of using different forms of marijuana (such as inhaled [smoked or vaporized], tincture, sprays, suppositories, oils), among individuals prescribed medical marijuana.

- Document and evaluate statewide referral patterns, reported indications, benefits and adverse events with use of medicinal marijuana as a function of age, gender, race, locale, co-morbidities, other risk exposures, socio economic status and provider.

- Characterize public safety concerns related to medical marijuana use and evaluate existing quality assurance, safety, packaging and current standards for dispensing and patient education regarding medical marijuana products.

- Perform ecological evaluation contrasting statewide cause-specific death and morbidity rates in the calendar year preceding and year following passage of the law.

- Utilize the State of Florida Medical Marijuana Registry to characterize the health effects of medical marijuana dose and mode of administration on related overdoses and poisonings, traffic accidents, work productivity, depression, fatigue and other health endpoints.

1b. Education to improve knowledge of Health Professionals and the Public:

- Survey State of Florida health care providers on current state of knowledge regarding state medical and federal medical marijuana laws, perceived indications for medical marijuana, related evidence base, benefits and risks, barriers and facilitators to referral.

- Identify gaps in medical marijuana knowledge and related skills of health care and public health professionals and develop education programs to address these gaps.

- Evaluate public knowledge and understanding of known risks and benefits of medical and recreational marijuana use. Identify educational needs, develop educational programs and evaluate the impact over time.

1c. Laboratory Research:

Apply state-of-the art techniques to screen phytochemical components of marijuana (and additives) and validate the potential targets *in vitro* and *in vivo* to inform potential use in specific medical use indications.

Provide laboratory based evidence to determine whether medical marijuana use synergizes or antagonizes with prescribed drugs. Investigate the molecular mechanisms of these interactions and their clinical implications.

1d. Clinical Research:

- Informed by laboratory and preclinical studies, investigate the pharmacokinetic and pharmacodynamic properties of medical marijuana, modes of delivery, different concentrations, in various populations, including the dose–response relationships of marijuana to other cannabinoids as monotherapies and in combination with standard treatment modalities.

- Conduct well-controlled phase I-III trials on the potential health effects of using different forms of marijuana, such as inhaled (smoked or vaporized), tincture, sprays, suppositories, oils etc.) targeting specific unstudied and understudied health endpoints.

1e. Health Policy and Health Economics Research:

- Identify models, including existing state marijuana policy models, for sustainable funding of national, state, and local public health surveillance systems.

- Investigate the economic impact of medical marijuana use on state public health and health care systems, health insurance providers, and patients.

Objective 2: Professional and Public Education

Build infrastructure to increase knowledge and understanding of current evidence on the short- and long-term health effects of marijuana use among health care professionals, policy makers, growers, marijuana dispensaries/pharms, public, patients and caretakers.

2a. Health Care Guidelines

- Coalesce and organize national resources, including clinical practice guidelines [National Institute of Health(NIH) -National Institute of Drug Abuse, National Cancer Institute(NCI), National Institute of Ageing (NIA), American Society of Clinical Oncology (ASCO), American Academy of Pediatrics (AAP), American Psychological Association (APA), etc] and develop additional resources to improve knowledge on medical

marijuana, targeting medical, pharmacological, nursing, paramedical and other health care professional groups in the state of Florida.

- Provide access to the most up-to-date research and clinical guidelines resources to guide clinical practice from national sources, including research results conducted through the Coalition.

    NCI:
    https://www.cancer.gov/about-cancer/treatment/cam/hp/cannabis-pdq

    NIDA:
    https://www.drugabuse.gov/publications/research-reports/marijuana
    https://www.drugabuse.gov/publications/drugfacts/marijuana

2*b. Research Quality*

Conduct an annual, interactive workshop of multi-disciplinary leaders, to develop research standards and benchmarks to guide and ensure the production of high-quality medical marijuana research. Workshop objectives will include, but will not be limited to:

- The development of a minimum dataset for observational and clinical studies, standards for research methods and design, and guidelines for data collection methods.
- Adaptation of existing research-reporting standards to the needs of medical marijuana research.
- The development of uniform terminology for clinical and epidemiological medical marijuana research.
- The development of standardized and evidence-based question banks for clinical research and public health surveillance tools.
- Determining the capacity to collect and reliably interpret data from diagnostic classification codes in administrative data (e.g., International Classification of Diseases-10).
- The establishment and utilization of state-based testing facilities to analyze the chemical composition of marijuana and products containing components of marijuana or other cannabinoids.
- The establishment and utilization of standardized protocols to analyze the chemical composition of marijuana and products containing components of marijuana.
- The development of novel diagnostic technologies that allow for rapid, accurate, and noninvasive assessment of marijuana exposure and impairment.
- Strategies for surveillance of harmful effects of marijuana for therapeutic use.

2c. Public Education

Coalesce and organize national resources (NIH-NIDA,NCI,NIA; ASCO, AAP, APA, ANA etc),and develop additional resources to improve current knowledge of the general public, patients and caretakers in the State of Florida on medical marijuana use (both beneficial and harmful effects) for specific indications.

Provide access to the most up-to-date research and clinical guidelines resources that inform clinical practice from national sources.

https://www.cancer.gov/about-cancer/treatment/cam/patient/cannabis-pdq

https://teens.drugabuse.gov/drug-facts/marijuana

Objective 3: Regulatory Issues

Convene a committee of experts including researchers, clinicians (ASCO, APA, ANA), regulatory (DEA, FDA, DOH) and funding organizations (State of Florida, NIH-NIDA,NCI,NIA) and task them to produce objective and evidence-based reports that fully characterize the impacts of regulatory barriers and propose strategies to mitigate these barriers.

Committee objectives include, but are not be limited to proposing strategies to address:
- Patient barriers to the use of medical marijuana for approved indications.
- Clinician barriers to patient care.
- Research barriers, including access to research-grade marijuana.