NIH Resource Center for Cannabis and Cannabinoid Research (R3CR) Stakeholder

Meeting Summary

May 21, 2026

Background

Use of the female cannabis (*Cannabis sativa* L.; Cannabaceae) inflorescence for both recreational and medical purposes has increased exponentially during the past decade. As of 2025, millions of people acknowledge using cannabis products for medical purposes to treat an array of conditions. The growing recognition of the need for systematic non-clinical and clinical research on cannabis and cannabis-derived constituents is reflected in the guidance provided by several groups, including the Food and Drug Administration (FDA), National Institutes of Health (NIH), and Drug Enforcement Agency (DEA). The many barriers to research on cannabis efficacy and safety are highlighted in several publications.

The following challenges have been reported:

- Issues related to Investigational New Drug (IND) applications.
- Limited and inconsistently documented studies.
- Lack of validated analytical methods to measure cannabis-derived compounds.
- The increasing diversity of cannabis products.
- Lack of medical education on cannabis for health care providers.

Reproducibility of non-clinical and clinical research is critically dependent on using well-characterized investigational materials, which may include cannabis plant biomass, cannabis-derived extracts, or purified cannabinoids, as well as oral or topical consumer products.

This stakeholder meeting was intended to further the objective of the NIH Resource Center for Cannabis and Cannabinoid Research (R3CR) to support investigators involved or interested in cannabis research by providing guidance and information to help address barriers and challenges related to regulations, research materials, and proposal development and to successfully generate more rigorous scientific evidence across both non-clinical and clinical research domains.

Opening Remarks

Dr. David Shurtleff, Acting Director of the National Center for Complementary and Integrative Health (NCCIH), welcomed attendees to the Stakeholder Forum, reviewed NCCIH's mission and vision, and outlined NCCIH's partnership with the National Cancer Institute (NCI), National Institute on Aging (NIA), and the National Institute on Drug Abuse (NIDA). Dr. Shurtleff highlighted the adverse effects and therapeutic benefits related to cannabis used for medical purposes, emphasizing the evolving regulatory landscape, NIH research priorities, and the challenge of keeping pace with a rapidly expanding industry.

Dr. Susan Weiss, Director of the Extramural Research Division at NIDA, highlighted the DEA's recent rescheduling of marijuana. She provided an overview of the current regulatory landscape and discussed the challenges facing researchers and physicians navigating complex registrations with DEA and the FDA. Dr. Weiss reviewed NIDA's research priorities, including cannabis pharmacology, the biology of the endocannabinoid system, polysubstance and lifetime exposures, and exposures in sensitive populations such as developing fetuses and pregnant women. She highlighted the importance of researchers obtaining valid data on products, exposures, and impacts.

Dr. Alexis Bakos, Program Director at NIA, discussed NIA's focus on fostering connections between investigators and stakeholders as cannabis use continues to rise in young women and older adults. She noted the unique needs of older adults, who face increased health risks as they age. Dr. Bakos reviewed interdisciplinary NIH initiatives in palliative care and citizen science, highlighted the importance of researching cannabis use across the lifespan, and noted how R3CR serves to improve the lives of Americans.

Dr. Gary Ellison, Acting Director at the Division of Cancer Control and Population Sciences (DCCPS) at NCI, reviewed the DCCPS cancer research support areas. He summarized previous NCI initiatives focused on cancer patients and cannabis use, including the 2020 research symposium. Due to the lack of information on the impact of cannabis use during cancer treatment, NCI is assessing the benefits and risks to cancer patients, which will help inform future clinical trials. The goal is to generate scientific evidence and develop best practices for administering cannabis and cannabinoids to cancer patients and survivors in clinical trials. Dr. Ellison emphasized the need for validated measurement tools, IND application support, and a diversified line of well-characterized cannabis products for research purposes.

NIH R3CR Vision and Goals

Dr. Patrick Still, Program Director, NCCIH, reviewed NIH investments in cannabis and cannabinoid research, including projects aimed at creating real-world evidence to better understand cannabis in the context of pain management and cancer. He shared NCCIH's Notice of Funding Opportunity to study non-addictive natural products for pain management, reviewed the NIH U24 Cooperative Agreement, and summarized the results from NIH's 2020 Request for Information (RFI) and 2022 PI meeting related to cannabis research needs. Dr. Still emphasized the value of R3CR providing a shared research infrastructure to help address barriers and provide tools and regulatory clarity to researchers, helping generate reproducible science that informs public health initiatives.

RC3R Core Overview and Implementation Updates

Dr. Ikhlas Khan, R3CR Director and Professor of Pharmacognosy at the University of Mississippi (UM), provided the background and overview of the RC3R, including the Research Support Core, Research Standards Core, and Regulatory Guidance Core. He emphasized the importance of obtaining fit-for-purpose research, shared highlights and progress from the R3CR's first year, and discussed the value of uniting voices and providing up-to-date regulatory information to stakeholders.

Regulatory Guidance Core

Donald Stanford, Assistant Director of the Research Institute of Pharmaceutical Sciences at UM, provided an overview of the Regulatory Guidance Core, including milestones and accomplishments, and shared recent updates to the regulatory status of cannabinoids and medical marijuana. He discussed the impacts of Public Law 119-37, Division B; Executive Order 14370; and the DEA Final Rule on Schedules of Controlled Substances.

Research Standards Core

Dr. Nandakumara Sarma, Research Standards Core Lead and Director of Dietary Supplements and Herbal Medicines at the United States Pharmacopeia (USP), presented the goals of the Research Standards Core, including support for the reproducibility and comparability of research and guidance for analytical methods and testing labs to help address barriers related to characterizing materials. He reviewed known quality concerns, such as the variability in products and terminology, potency inflation, the diversity and complexity of chemical matrices, and scarcity of research-grade materials. Dr. Sarma reviewed milestones for the Research Standards Core, such as engaging stakeholders and compiling a list of analytical methods and best practices.

Research Support Core

Dr. Mary Paine, R3CR Research Support Core Lead and Professor in the Department of Pharmaceutical Sciences at Washington State University (WSU), reviewed the goals for the Research Support Core, provided a timeline of activities, and shared that R3CR is now a member of the Association of Cannabis Research Centers (ACRC). Dr. Paine reviewed the criteria and submissions for the initial round of seed funding. She noted applications were selected based on responsiveness, significance, investigators and environment, approach, and feasibility, as described in Table 1. Dr. Paine noted that the Request for Application (RFA) for the second round of funding would be released and shared on the R3CR website, www.r3cr.org, in late summer 2026.

Table 1. Seed Funding Evaluation Criteria

Category	Evaluation Criteria
Responsiveness	• Does the application clearly address regulatory or logistical barriers to cannabis research? • Are the proposed activities non-research enablement (not hypothesis-driven research)?
Significance	• Will completion of the proposed activities position the team for competitive NIH funding?
Investigators & Environment	• Are the PI and team well suited to fulfill their roles? • Do they have appropriate experience and training? • Are resources and institutional support available to complete the proposed activities?
Approach	• Are the overall strategy and operational plan appropriate for completing the proposed activities? • Are potential problems, alternative strategies, and benchmarks for success presented?
Significance	• Are the proposed activities achievable within one year, with a budget ≤ $50K and timeline? • Is the budget fully justified and reasonable in relation to the proposed activities?

Seed Funding Projects: Emerging Research Directions

Dr. Paine introduced the seed funding awardees. Awardees presented their grant-funded projects, which are summarized in Table 2.

Discussion

Awardees discussed the following topics:

- The possibility of integrating microbial control testing and third-party laboratory test data into stability programs and databases.
- The importance of communicating research findings in a timely fashion (i.e., before the publication of peer-reviewed articles).

Table 2. First Round of Seed Funding: Awardees, Project Descriptions, and Goals

Awardee	Category	Project Description	Goals
Dr. Desmond Mortley, Tuskegee University	Regulatory	Establishing organizational infrastructure for cannabis research	Develop a DEA-ready research environment

Dr. Danielle Smith, Health Research Inc.	Regulatory	Enhancing organizational capacity for schedule I cannabis research	Streamline research and compliance efforts
Dr. Tess M. Eidem, University of Colorado Boulder	Tool development	Building a public health database to advance cannabis research and policy	Integrate health, regulatory, occupational, and contamination data into a standardized framework
Dr. Mohamed Radwan, UM	Study materials	Acquiring stability chambers to enable controlled examination of environmental effects on product purity, dosage, and safety	Enable systematic evaluation of the stability of cannabinoids, extracts, and finished products
Dr. Miyabe (Christina) Shields, Northeastern University	Regulatory	Streamlining NIH-aligned cannabis-related grant submissions through the development of compliance guidance and internal fast-track procedures	Create standardized documentation and workflows to facilitate basic research
Dr. Anthony Ferrari, Sym Sciences	Study materials, regulatory	IND-enabling cannabinoid health outcome platform for multi-site clinical evaluation	Develop IND-ready materials and standardized IND templates and documentation
Dr. Bradley Conner, Colorado State University	Study materials	Developing legal market cannabis products to be used in research studies	Develop, test, package, and distribute standardized cannabis products

Navigating the Evolving Regulatory Landscape

Donald Stanford reviewed the efforts to place marijuana in schedule III of the Controlled Substances Act; outcomes resulting from the DEA Final Rule, published on April 28, 2026; the Single Convention Treaty on Narcotic Drugs and draft *Guidelines on the International Drug Control Requirements for the Cultivation Manufacture and Utilization of Cannabis for Medical and Scientific Purposes*; regulatory requirements for conducting different types of medical cannabis studies; and requirements for Mississippi's state medical cannabis

program. He noted the importance of DEA's June 29, 2026, administrative hearing and shared that R3CR plans to provide stakeholders with information on the following topics:

- Schedule III registrations for medical cannabis producers.
- The schedule I to schedule III transition for researchers and manufacturers.
- Clinical-grade and research-grade quality advice for manufacturers.
- Real-world evidence studies.

Mr. Stanford emphasized the following:

- Rescheduling cannabis will reduce barriers to research.
- Rescheduling does not affect FDA requirements for an IND.
- Researchers and institutional administrators must be aware of changing regulations as well as the regulatory pathways for product development.

Panel Discussion

Donald Stanford led a panel discussion with Dr. Cassandra Taylor, Public Health Advisor at FDA, and Dr. Robert Welch, Director of the National Center for Cannabis Research and Education at UM. Panelists discussed the following topics:

Barriers to and Requirements for Clinical-Grade Cannabis Products

- The legal definition of a "drug."
- Requirements for clinical studies and INDs.
- Best practices for interfacing with FDA offices, including pre-IND meetings.
- The challenge and importance of obtaining the necessary information for the chemistry, manufacturing, and controls (CMC) for botanicals.
    - CMC requirements for drug applications (e.g., information on starting materials, solvents, and byproducts).
    - The impact of different drug indications on the requirements to meet minimum safety standards.
    - The benefit-risk analysis for protecting study participants (i.e., the differences between administering drugs to sensitive populations versus healthy adults).

Barriers to and Requirements for Non-Clinical Grade Cannabis Products

- The importance of researchers getting involved with state groups that will be impacted by rescheduling (e.g., departments of health and industry groups).
    - The importance of understanding state requirements, jurisdictional laws, and local requirements for the quality of DEA-registered articles.

    - Leveraging resources, including The Cannabis Regulators Association (CANNRA), to better understand these legal requirements.
- The benefits of using International Organization for Standardization (ISO)-certified laboratories for projects such as isolating cannabinoids.

Full-Spectrum CBD Products: Research and Education Needs for Protecting Public Health

- The importance of avoiding confounded data, having in-depth knowledge of the products being administered to trial participants, and generating real-world evidence from research that benefits patients (e.g., patient outcome studies).
    - Tracking how patients are using products (e.g., what is being taken, how much is taken and how often, and the type of dosage form).
        - Providing this information to state legislators and healthcare providers.
- The value of educating healthcare providers and researchers through universities, non-profits, and public entities.

Synthetic Cannabinoids

- Additional regulatory requirements for new molecular entities (e.g., pharmacology and toxicology work and the requirements and guidelines for identifying and controlling impurities).
- The differences in impurity profiles for plant-based versus synthetic molecules.
    - Understanding manufacturing processes to evaluate potential safety risks from impurities and contaminants.

DEA-Approved Cannabis Growers and Peer-to-Peer Supply Network

Dr. Sarma led a panel, consisting of DEA-approved bulk manufacturer marijuana growers, in a discussion about connecting suppliers to researchers. Panelists discussed the following topics:

- Challenges related to the low demand for DEA-licensed cannabis materials for research use.
- Distinctions between DEA requirements for licensing and FDA requirements for researching and commercializing.
- Potential increases in funding opportunities due to rescheduling.
- The importance of selecting well-characterized products, dosages, and matrices to streamline applications and protocols.

    - The resources needed to fund stability programs, complete novel product testing and CMC sections, and produce Good Manufacturing Practices-compliant material that meets regulatory requirements.
        - The importance of considering approval requirements during IND development to conserve resources and minimize future work.
- The importance of optimizing research grant applications to improve success rates.

Dr. Taylor highlighted the importance of researchers and sponsors reviewing FDA's publicly available guidance before contacting FDA offices to discuss IND submissions. FDA's Cannabis and Cannabis-derived Compounds: Quality Considerations for Clinical Research Guidance for Industry outlines FDA's current thinking and provides references to regulations applicable to cannabis research.

RFI for Peer-to-Peer Network

Dr. Sarma reviewed the proposal to create a peer-to-peer network to enhance the research infrastructure for cannabis. The purpose of this peer-to-peer network is the exchange of cannabis and cannabis-derived constituents to facilitate collaborations and reproducible research. Attendees discussed the RFI for investigators' interests in and barriers to adoption of a peer-to-peer network for exchange of cannabis and its constituents. Dr. Sarma asked attendees to review and provide input for the RFI by June 15, 2026.

Aligning Center Resources with Research Community Needs

Dr. Paine opened the session by sharing the Research Support Core's goal of helping researchers overcome barriers in cannabis research. She posed three questions: 1) How can we overcome the research barriers more efficiently? 2) What are the research priorities for cannabis science? 3) How can cannabis science be effectively disseminated to stakeholders? Each panelist addressed one of these questions.

The Cannabis Conundrum: Applying for a DEA Schedule I Human Research Certificate

Dr. Matt Layton, Professor of Translational Medicine and Physiology at WSU, reviewed the process for conducting human subjects research using a schedule I compound, IND exemption criteria, and impacts of rescheduling on researchers. He shared data on the impact of fatigue, cannabis, opioids, and alcohol on sleep quality.

The Association of Cannabis Research Centers: Cannabis Research Priorities

Dr. Devan Kansagara, Professor of Medicine at Oregon Health & Science University, provided updates from the Association of Cannabis Research Centers (ACRC) and the Systemically Testing the Evidence on Marijuana (STEM) project. He reviewed survey results on 19 different cannabis research priorities, grouped by their Translational Research Spectrum research areas (shown in Table 3).

Table 3. Research Priorities Identified by the ACRC Survey

Translational Research Area	Research Priority
Basic Science and Preclinical Studies	• Refine translatability of models • Pharmacokinetics/pharmacodynamics of minor cannabinoids • Pharmacogenomics and biomarkers • Better standards
Clinical Studies	• Minor cannabinoids • Lifespan studies • Long-term outcomes • Anxiety disorders
Clinical Implementation and Methods	• Better placebos • Big data / data harmonization • Measures harmonization • Dosing standards • Multimorbidity
Public Health	• Cannabis and parenting, pregnancy, and early childhood development • Environmental and occupational health impacts • Impacts of cannabis policy on health and vulnerable communities • Standardization of dosing, packaging, testing, labeling, and nomenclature • Information, education, and messaging • Measurement of health outcomes

Overcoming Digital Dissemination Barriers in Cannabis Research

Ms. Rebecca Cooney, Professor of Communication at WSU, discussed challenges related to the moderation of cannabis content on digital platforms; shared media and messaging tools and a strategic communication roadmap; and discussed strategies to avoid automated content moderation by bots, algorithms, and digital restrictions. She emphasized the importance of anchoring cannabis messaging in science and research,

focusing on authoritative platforms, using bridge keywords, measuring communication effectiveness, and adapting digital communication strategies over time.

Discussion

Attendees discussed challenges related to obtaining INDs for cannabis research and reviewed the criteria to consider when applying for an exemption from IND requirements. Dr. Taylor emphasized the importance of reviewing FDA's Guidance and decision tree, understanding applicable laws and regulations, and understanding the exemption criteria listed in the Code of Federal Regulations at 21 CFR 312.2.

Attendees discussed the challenge of sharing cannabis research on social media platforms that are designed to entertain users and increase engagement, not communicate science.

Concluding Remarks

Amanda Cowley, Chief Growth Officer and Executive Vice President of Programs, Regional Operations, and Strategy at USP, discussed USP's commitment to cannabis quality since USP's first publication of a cannabis monograph in 1850. She discussed USP's work to provide quality standards, analytical methods, and tools that enable reproducible research and mitigate harm due to substandard and contaminated products.

Dr. Still discussed NIH's ongoing collaborative efforts and commitments to advancing cannabis and cannabinoid research and the infrastructure that makes the science reproducible, rigorous, and useful.

Next Steps

The R3CR will release the second seed funding RFA. Stakeholders can expect its release in late summer 2026. She encouraged attendees to contact the R3CR (info@r3cr.org) if interested in serving as a reviewer.

The peer-to-peer RFI closed on June 15, 2026.

Stakeholders are encouraged to follow R3CR on social media and sign up for R3CR updates at www.r3cr.org.