CLEVER LEAVES CHANGE LIVES CAMPAIGN
RESEARCH AND DEVELOPMENT AND CLINCAL TRIAL REQUEST FOR PROPOSAL FORM (RFP)

CONTACTS:

Letters of intent should be sent to PCLLOI@cleverleaves.com

Full applications should be sent to PCLProposals@cleverleaves.com

All other inquiries should be directed to PCLInquiries@cleverleaves.com

Section I: Overview

Purpose:

Although the field of medical cannabis research is growing rapidly globally, there are still too few randomized controlled trials in the United States to guide clinical decisions domestically. Most importantly, there is an insufficient supply of legal, high-quality, GMP certified medical cannabis to study. Moreover, because the majority of current cannabis studies tend to focus on only testing the cannabis flower due to the scarcity of high-quality cannabis oils and extracts, there is currently an insufficient degree of clinical study of the potential benefits of cannabis oils as a non-combustible cannabis API and therapeutic medicine.

Furthermore, due to a lack of available high-quality cannabis ingredients, many clinical trials are under-resourced with respect to the appropriate amounts of APIs and therefore tend to be small with limited populations and short periods of follow up. This paucity of quality clinical research and data is a significant impediment to advancing the science of medical cannabis. Thus, more—and larger—randomized controlled trials are needed, and clinical studies must ensure that they are only using the highest-quality EU-GMP or INVIMA GMP certified cannabis flower and extracts to ensure the quality of the research study and any resulting medicines that may be derived therefrom.

In order to help advance the research into the potential medical benefits of the cannabis plant in the U.S., Clever Leaves has committed to providing up to US $25 million in cannabis-derived ingredients and finished products for use in high-quality research that will advance the field of medical cannabis in the United States. Key goals of this initiative are to:

- Promote high-quality interventional cannabis research;
- Encourage innovation in data collection methods that facilitate the efficient creation of generalizable knowledge through non-traditional research designs (e.g. adaptive and pragmatic trials);

- Encourage the use of innovative and efficient strategies for collecting patient-reported outcomes;
- Facilitate use of subsequent data by diverse stakeholders with research questions that will advance the science of medical cannabis;
- Guide the cannabis research field toward standardizing data elements and move the field toward more consistency in instruments, variables, and methods of data collection; and
- Support and encourage women and underrepresented minority scientists and researchers working in the cannabis space and in academia.

Key Milestone Dates:

- Posted Date: June 28, 2021
- Open Date (Earliest Submission Date): June 28, 2021
- Letter of Intent Due Date: The first day of every month for Track A. (No LOI needed for Tracks B and C).
- Application Due Date(s): For Track A: the first day of every month, by 5:00 PM Eastern Standard Time. For Tracks B and C, applications will be accepted on a rolling basis.
- Scientific Merit Review: Rolling

Tracks:

- Track A: Unfunded studies for which cannabis product is needed.
- Track B: Studies that have already undergone peer review, for which cannabis availability is posing a significant obstacle that limits the likelihood of success. (Brief proposal and expedited review).
- Track C: Planned studies for which an investigator is seeking a letter of support to be included in a proposal to a funding organization. Project Change Lives will provide a letter of support indicating a commitment to provide the necessary cannabis product, contingent on funding. (Brief proposal and expedited review).

Required Application Instructions: Clever Leaves welcomes applications to participate in the Change Lives initiative from all eligible recipients of its products in the United States. However, it is critical that applicants follow all of the instructions in this form carefully. Conformance to all instructions is required and strictly enforced. Applicants must read and follow all application instructions.

Applications that do not comply with these instructions may be delayed or rejected.

Section II: Award Information

Funds Available and Anticipated Number of Awards: Clever Leaves expects to commit up to $25 million of cannabis-derived ingredients and finished products to the Change Lives initiative over the next 5 years. Any future year contributions beyond the initial 5-year period will be made at the sole discretion of Clever Leaves and will depend on the annual budgeting decisions of Clever Leaves.

Award Budget: Although there are no fixed limits on the amount or cost of cannabis product to be used in a study, the proposal should carefully justify the amount requested. Any potential funding of medical cannabis is for cannabis-derived products only, accessed via Clever Leaves and official importation channels.

Award Project Period: Applications may request a project duration of up to three (3) years. Investigators who wish to request a longer duration should contact the Director of the Change Lives Campaign, and Chief Medical Advisor (Dr. David Casarett) before submitting a proposal.

Section III: Eligibility Information

Eligible Organizations

- Public/private Institutions of Higher Education
- Other not-for-profit institutions
- Clinical practice groups or clinical consortia
- Contract Research Organizations
- Pharmaceutical Companies

Eligible Individuals (Program Director/Principal Investigator): Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individual Schedule I DEA licenses are required, as are all applicable state approvals.

Number of Applications: Applicant PIs may submit only one application. There is no limit to the number of applications that can be submitted by an institution.

Section IV: Letter of intent (Track A only)

Letter of Intent: Although a letter of intent is required for Track A, it is not binding, and does not become part of the review of a subsequent application, if applicable. The information that it contains allows staff to estimate the potential review workload and plan the review. A Track A LOI should include the following information:

- Descriptive title
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Unstructured abstract with Specific Aims

Section V: Brief application (for Tracks B-C)

Investigators should submit:

- A document that contains:
    - Descriptive title of the project
    - Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
    - Names of other key personnel
    - Participating institution(s)
    - Abstract that includes background, aims, approach, and a specification of the type and amount of cannabis product required for the duration of the study

AND

- For Track B - a cover letter describing the funding award that the investigators have received, and a copy of the notice of award.

- For Track C - a cover letter describing the funding opportunity to which the investigators are applying.

Section VI: Application and Page Limitations (applies only to Track A):

PLEASE NOTE: Full applications are accepted only for Track A. (Other Tracks require only limited materials as described above.)

- **Unstructured abstract (1 page):** Please provide an overview of the goals, strategy, and objective of the proposed project.

- **Key personnel profiles (2 pages):** Include only the Principal Investigator(s) (PI(s)). Summarize background, skills, and qualifications. Please attach CV.
    - **Biographies of Key Personnel:** Use National Institutes of Health format (4 pages for each biosketch; unlimited total pages)

- **Description of Additional Personnel (2 pages):** Summarize background, skills, and qualifications of additional personnel followed by their Biographical Sketches. Biographical sketches do not count toward the page limit.
    - **Biographies of Other Personnel:** Use National Institutes of Health format (4 pages for each biosketch; unlimited total pages)

- **Project/Performance Site Location(s) Description (2 pages):** Describe resources available as they relate to the proposed projects. Pay particular attention to data security infrastructure, statistical support, space, administrative support, and computing resources.

- **Research Budget (3 pages):** Include line items for requested cannabis product, broken down by 6-month period in each grant year (up to 4 periods total, or longer with prior approval for a longer study duration). Explain any year-year change of more than 10%. Also specify how other research costs will be covered, including, but not limited to: recruitment/retention, data collection, data analysis, staff time, and investigator time.

- **Specific Aims (1 page):** Describe the theme and goals of the proposed project and how they will advance research and impact the cannabis research community by collecting, coordinating, and sharing data. Describe how the specific aims of the project will achieve these goals.

- **Research Strategy (5 pages):** Describe the approach to be used, methods, and key strategies. Key components should include, in order:
    - Background and significance
    - Description of preliminary work, including examples of the team's experience with subject recruitment/retention in cannabis-related studies
    - Setting and subjects, including eligibility criteria and plans for recruitment, with an emphasis on additional steps to enhance recruitment of underrepresented minorities. This section should include a concise description of anticipated recruitment numbers and timeline.
    - Data collection: Investigators should review the CRC list of recommended instruments (available on ProposalCentral), selecting them whenever possible. Additions are acceptable but substitutions (different instrument for a given domain) are discouraged.
    - Data analysis
    - Sample size/power calculations
    - Plan to safeguard data privacy

- **Dissemination (1 page):** Describe a plan for dissemination of results of the completed study. Methods, techniques, and technologies to be used for proposed activities must be defined as well as the targeted audience or participants. Issues of cultural sensitivity with regard to the intended audience must be addressed. When appropriate, activities must be designed to effectively reach scientifically, and medically underserved populations/communities and/or subgroups based on age or gender. If applicable, describe the planned dissemination of scientific knowledge for the purpose of disparities in access to cannabis among racial and ethnic minority and other health disparities populations.

- **Administrative services (1 page):** This section should describe responsibility for the administration of the budget as well as day-to-day operations involving finances, personnel, planning, and budgeting.

- **Human Subjects (unlimited pages):** A clear description of plans for informed consent, research subject monitoring and safety, and data privacy. Institutional Review Board approval should be stated (with protocol number) or listed as pending.

- **Institutional Letter of Support (unlimited pages):** A letter from an institutional representative should concisely describe the institution's support for the proposed project. This letter need not duplicate other elements of the proposal but should instead provide a level of assurance that key elements such as infrastructure access, space, and protected time will be made available by the institution should the proposal be selected for funding.

- **Optional Letters of Support (unlimited pages):** Letters of support should be included in this section. Include a table summarizing the names, institutions and role, *e.g.*, collaborator, consultant, clinician.

Section VII: Application Review Information (Track A only)

Project Change Lives has assembled a panel of reviewers who are recognized experts in clinical cannabis use, cannabis researchers, and research methods. Reviewers will score applications using standard National Institutes of Health (NIH) categories (e.g. significance, impact, approach, etc). Final decisions about funding will be made by Clever Leaves staff and the Senior Medical Advisor.

- **Overall impact:** Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on cannabis research, in consideration of the following review criteria:

- **Significance:** Is the proposed project able to make a contribution to the field of medical cannabis research?

- **Investigator(s):** Are the PI(s) and collaborators well-suited to the project? If there are multiple PIs, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

- **Innovation:** Does the proposal challenge and seek to achieve the goals of the CRC by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

- **Approach:** Does the proposal include:
    - A compelling case that the project, if carried out, is likely to successfully accomplish the proposed aims?
    - A description of preliminary work that makes the case for plausibility and feasibility?
    - Adequate justification of the recruitment goals and timeline?
    - A plan for ensuring adequate and appropriately diverse recruitment?
    - A clear plan for data collection and a convincing case that the planned data collection will be feasible?
    - A robust plan for data analysis that is consistent with the proposed sample size?

- **Environment:** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the proposed?

- **Protections for Human Subjects:** Are there rigorous procedures in place to ensure data security and privacy? (e.g. HIPAA requirements)

- **Budget and Period of Support:** Reviewers will consider whether the requested cannabis product is appropriate, and whether there is sufficient evidence of collateral support (financial and in-kind) to make the proposed project possible. The proposed budget will receive a merit descriptor (acceptable or unacceptable).

- **Dissemination:** The dissemination plan (e.g. journal manuscripts, poster presentations, social media) will receive a merit descriptor (outstanding, acceptable or unacceptable) based on the presence of plans to ensure dissemination of results broadly and to targeted audiences.