Information Form
For the Proposed Use of Hemp or Hemp-Derived Products in Research at the University of Colorado Boulder

The 2018 Farm Bill (pdf) directed the US Department of Agriculture (USDA) to establish a national regulatory framework for Hemp* production in the United States. USDA published a Final Rule on January 19, 2021, that provides regulations for the production of Hemp in the United States and is effective on March 22, 2021.

USDA does not regulate:

- The manufacturing-side of Hemp
- Transportation of Hemp
- The creation of products made from Hemp
- FDA is the main federal entity that regulates product made for human and animal consumption or medicine.

CU's review will ensure adherence to federal and state rules and regulations applicable to research projects that use Hemp or Hemp-derived products.

When do Use this Application Form:

This form must be completed in its entirety if a researcher is planning on conducting a research project involving Hemp or a Hemp-derived product obtained from a vendor that has not been pre-approved. If a CU researcher is planning a research project involving Hemp or a Hemp-derived product obtained from a pre-approved vendor, only page 3 must be completed. A list of pre-approved vendors can be found HERE (can hyperlink it once page exists).

Documents to be Submitted with this Application Form:

- Protocol or summary of proposed research
- Completed attestation section from supplier
- Documents requested in the following sections of this form

* The 2018 Farm Bill defines Hemp as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." (7 U.S.C. § 1639o(1))

Additional Information Form for Hemp or Hemp-Derived Products Only

If the research will include an IND, the following documents must also be submitted:

- Detailed information about the final product, its composition (e.g. CMC section of IND, vendor COA, product sheet) and storage requirements
- Instructions and/or standard operating procedures and product accountability logs to be used by the research team

Once completed, please submit this form for review to the Controlled Substances Used in Research Program Office in the Office of Research Integrity at Isabel.Weber@colorado.edu.

Additional Information Form for Hemp or Hemp-Derived Products Only

To assist the University with its review, please provide the following information:

(to be completed by Applicant)

Name and email address of Applicant (and PI if not the same) _____

_____

1. Type of research: ☐ Basic ☐ Animal ☐ Human

2. Funding source(s) for the project:

3. Describe the plan for obtaining or procuring the Hemp or Hemp-derived product (e.g. CBD extract). If obtaining Hemp or Hemp-derived product from pre-approved vendor, please include their information here:

4. Describe who will manufacture the final active formulation(s) for this study:

5. Describe the plan for obtaining or procuring a placebo product (if applicable):

6. Describe the final formulation that will be administered (concentration of relevant compounds, dose, route, frequency):

7. Provide additional information that seems relevant to this project:

Hemp Supplier Attestation Section

(to be completed by the Hemp/Hemp-product supplier)

This section only needs to be completed is using a vendor that is not pre-approved.

I attest to the following (check all that apply):

☐ Hemp used for this project is grown in compliance with the 2014 Farm Bill and registered in the following Industrial Hemp Pilot Program (only acceptable until January 1st, 2022)

- Enter State_____
- Enter Registration information_____

☐ Hemp used for this project is grown in compliance with the 2018 Farm Bill and registered in the USDA approved (required after January 1st, 2022)

☐ U.S Domestic Hemp Production Program (enter state) _____

Enter Supplier's Registration information_____

OR

☐ State Hemp Production Plan for (enter state) _____

Enter Supplier's Registration information_____

If more than one source of Hemp is used in the manufacture of the research product, provide details here:

☐ Hemp and/or final Hemp-derived product were tested for THC levels at the following lab, and THC levels were less than 0.3%.

Hemp:

- Lab name and address_____
- DEA CS-1 license #_____ (required after Dec 31.2022)
- COA for Hemp ☐ is ☐ is not provided

Hemp-derived product (e.g. CBD extract):

- Lab name and address_____
- DEA CS-1 license #_____ (required after Dec 31.2022)
- COA for Hemp-derived product ☐ is ☐ is not provided

☐ Supplier has a federally insured bank account with [Bank Name and Address] _____

_____

_____

☐ Supplier is not a Direct Beneficial Owner of a Retail Marijuana Establishment or a Medical Marijuana Business as these terms are defined in Colorado Senate Bill 16-040; or a commercial grower, processor, distributor, or seller of Marijuana.

☐ If the research will include an IND, the Supplier will provide the Chemistry, Manufacturing, Controls (CMC) information and will provide responses to FDA requests related to my product and processes in a timely manner.

I hereby attest that:

- **The information provided above is accurate**
- **All Hemp-derived product provided was collected in accordance with all applicable laws and policies governing the growing, distribution and procurement of Hemp.**

Supplier Signature **Date**

Signatory Title

Company representing