AN ACT relating to ibogaine research in the Commonwealth, making an appropriation therefor, and declaring an emergency.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

As used in Sections 1 to 5 of this Act:

(1) "Department" means the Department of Agriculture;

(2) "Drug developer" means a for-profit, nonprofit, or public benefit corporation engaged in drug development and manufacturing that has established an ibogaine drug development agreement with at least one (1) additional state with a plan to conduct drug development clinical trials to obtain United States Food and Drug Administration approval for use of ibogaine; and

(3) "Ibogaine":

(a) Means a crystalline alkaloid psychogenic compound obtained from the Tabernanthe iboga plant; and

(b) Includes any of its derivatives or analogs in any form, whether existing or as-yet to be developed.

➔SECTION 2. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

(1) There is hereby established in the State Treasury a trust and agency fund entitled the ibogaine research and intellectual property fund, to be administered by the department for the purpose of allowing the department to enter into a public-private partnership with a drug developer to conduct a clinical drug development trial or trials related to the use of ibogaine for the treatment of opioid use disorder, co-occurring substance use disorder, or any other neurological or mental health condition for which ibogaine demonstrates efficacy.

(2) The fund may receive state appropriations, gifts, grants, federal funds, and any

other funds, both public and private. Moneys deposited in the fund are to be used for the purposes set out in Sections 1 to 5 of this Act.

(3) Notwithstanding KRS 45.229, any unallocated or unencumbered balances in the fund shall be invested as provided in KRS 42.500(9), and any interest or other income earned from the investments, along with the unallotted or unencumbered balances in the fund, shall not lapse but shall be carried forward into the next fiscal year.

➔SECTION 3. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

(1) Before the department may contract with a drug developer, the drug developer shall provide the department with:

(a) A detailed description of the drug developer's strategy for obtaining approval for the drug development clinical trials from the United States Food and Drug Administration and a detailed drug development clinical trial design, including a description of the composition of the consortium's drug development clinical trial team and the expertise of the team members;

(b) Protocols for clinical trial participant recruitment, patient screening criteria, administration, after-care, and post-acute treatment support;

(c) A plan to seek a breakthrough therapy designation for ibogaine from the United States Food and Drug Administration under 21 U.S.C. sec. 356;

(d) Financial disclosures necessary to verify that the drug developer is prepared to meet its full obligations under this section; and

(e) Certification of an existing ibogaine drug development agreement with one (1) or more other states or state-sponsored consortiums.

(2) Before the department may contract with a drug developer, the department shall negotiate a contract requiring the drug developer to substantially agree to:

(a) Match the Commonwealth's investment in drug development clinical trials

with ibogaine with an equal amount of additional funding and to devote this total amount in drug development clinical trials conducted within the Commonwealth. These trials shall exclusively use in-state clinicians, facilities, and study participants;

(b) Provide reports as specified under Section 4 of this Act;

(c) Establish a plan to ensure broad and accessible ibogaine treatment access to patients within the Commonwealth following approval of ibogaine by the United States Food and Drug Administration by diverse means, including but not limited to:

1. Providing priority access to ibogaine treatment to residents of the Commonwealth;

2. Seeking third-party payor approval for ibogaine treatment within the Commonwealth;

3. Developing means of access to ibogaine treatment within the Commonwealth for uninsured and low-income individuals; and

4. Training and credentialing medical providers within the Commonwealth to administer ibogaine treatment; and

(d) Provide a plan to recognize the Commonwealth's economic interest in the intellectual property generated over the course of the multistate drug development clinical trials with ibogaine, consisting of a share of the proceeds from said intellectual property which is proportional to the Commonwealth's contribution to the total cost of the multistate drug development trials, and to deposit the state's share of those proceeds in the ibogaine research and intellectual property fund established in Section 2 of this Act at agreed-upon intervals during the period for which the drug development clinical trials are funded and during any subsequent period of commercialization.

(3) In negotiating a contract with the drug developer, the department may agree to additional terms and make reasonable deviations from the requirements of this section as long as the resulting contract is fair and creates substantially equivalent value for the Commonwealth.

(4) For purposes of this section, intellectual property rights and other commercial rights arising from multistate drug development clinical trials with ibogaine include any of the following as related to these trials:

(a) Intellectual property, technology, and inventions;

(b) Patents, trademarks, and licenses;

(c) Proprietary and confidential information;

(d) Trade secrets, data, and databases;

(e) Tools, methods, and processes;

(f) Treatment models or techniques;

(g) Administration protocols; and

(h) Works of authorship.

➔SECTION 4. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

(1) The drug developer shall quarterly prepare and submit to the department a:

(a) Report on the progress of any multistate drug development clinical trials with ibogaine conducted pursuant to Sections 1 to 5 of this Act; and

(b) Financial status report, including information to verify expenditures of Commonwealth funds and required matching funds.

(2) The department shall submit an annual report by December 1 each year to the Legislative Research Commission for referral to the Interim Joint Committee on Health Services on the progress of the drug development clinical trials and their related financial status until the clinical trials are concluded.

➔SECTION 5. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO

READ AS FOLLOWS:

All receipts from the proceeds from the commercialization of intellectual property created through the public-private partnership created under Sections 1 to 5 of this Act shall be deposited into the ibogaine research and intellectual property fund established in Section 2 of this Act. Expenditures from the fund shall be used only for programs or research benefitting at-risk populations that suffer from conditions treatable with ibogaine, including but not limited to opioid use disorder, co-occurring substance use disorder, post-traumatic stress disorder, traumatic brain injury, and other neurological or mental health disorders.