

1 AN ACT relating to Ibogaine research in the Commonwealth.

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

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

5 *As used in Sections 1 to 4 of this Act:*

6 *(1) "Department" means the Department of Agriculture; and*

7 *(2) "Private entity" means an incorporated business licensed to operate in the*
8 *Commonwealth.*

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

11 *It is the declared policy of the Commonwealth that ibogaine is worthy of clinical*
12 *research, trials, and studies as a potential viable therapeutic treatment of opioid*
13 *dependence and any other co-occurring mental health disorders. The purposes of*
14 *Sections 1 to 4 of this Act are to:*

15 *(1) Promote the research and study of ibogaine as a treatment of opioid dependence*
16 *and any other co-occurring mental health disorders; and*

17 *(2) Promote the creation of an industry in the Commonwealth related to the study of*
18 *ibogaine.*

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

21 *(1) There is hereby established in the State Treasury a trust and agency fund entitled*
22 *the ibogaine research fund, to be administered by the department for the purpose*
23 *of allowing private entities that operate in the Commonwealth to partially cover*
24 *the costs of ibogaine research in the Commonwealth.*

25 *(2) The fund may receive state appropriations, gifts, grants, federal funds, and any*
26 *other funds both public and private. Money deposited in the fund is hereby*
27 *appropriated for purposes set out in Sections 1 to 4 of this Act.*

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

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

8 A private entity that applies for a distribution from the fund established in Section 3 of
9 this Act shall:

10 (1) Conduct and fund research in the Commonwealth related to:

11 (a) Ibogaine, including pharmaceutical development and the efficacies of
12 ibogaine for the treatment of opioid dependence and any other co-occurring
13 mental health disorders;

14 (b) The health effects, including the potential risks or side effects, of the use of
15 ibogaine; and

16 (c) The efficacy and potential health effects of various ibogaine delivery
17 methods;

18 (2) Review current and future ibogaine research literature, clinical studies, and
19 clinical trials;

20 (3) Monitor, to the extent that appropriate and sufficient data is available, patient
21 outcomes in states and countries that allow ibogaine research or usage; and

22 (4) Submit an application to the federal Drug Enforcement Administration to:

23 (a) Allow for it to conduct clinical research, trials, and studies of ibogaine as a
24 potential viable therapeutic treatment of opioid dependence and any other
25 co-occurring mental health disorders;

26 (b) Provide a detailed description of the planned strategy for securing an
27 approved "Investigation of New Drug" (IND) application from the Federal

1 *Drug Administration (FDA). IND approval from the FDA is a prerequisite*
2 *for clinical research and trials; and*
3 *(c) Provide a detailed clinical trial design including a description of the*
4 *composition of the entity's clinical trial team by expertise, clinical trial*
5 *participant recruitment plan, detailed patient screening criteria, cardiac*
6 *safety protocols, administration protocols, aftercare, post-acute treatment*
7 *support plan, and data integrity plan.*