

# **Addiction Research Institute, Inc.**

*Searching for Solutions<sup>sm</sup>*

[ARInstitute@mindspring.com](mailto:ARInstitute@mindspring.com)

26 Fox Hunt Drive, PMB 251  
Bear, Delaware 19701

Tel: 877-296-0046

Fax: 877-417-7394

---

## **RESEARCH GRANTS NOTICE OF AVAILABILITY**

Addiction Research Institute, Inc. (“ARI”) has allocated funds for a series of research grants (“Grants”) directed towards physicians and research institutions willing to participate in a Phase I/II clinical evaluation (the “Study”) of an investigational drug used in the treatment of opioid dependence. A synopsis of the Study is appended herewith.

A physician with clinical affiliation wishing to apply for a Grant under this Notice should be willing to act in the capacity of Principal Investigator (“PI”) for the Study. The physician/applicant should ideally possess a background in psychiatry and/or addiction medicine with experience in conducting clinical trials.

A research institution wishing to apply for a Grant under this Notice should be willing to provide all the necessary services for conducting the Study including in-patient and out patient services as required.

Any qualified physician or research institution wishing to apply for a Grant under this Notice should request an application and information package from ARI. Physicians should include their curriculum vitae. Requests may be submitted via facsimile or email.

\*\*\*

## STUDY SYNOPSIS

|                     |   |
|---------------------|---|
| <b>Title</b>        | An open, single dose, escalating fixed dose study of the safety and efficacy of IBOGAINE in opioid-dependent subjects.  |
| <b>Study Phase</b>  | Phase I / II  |
| <b>Name of Drug</b> | IBOGAINE - an alkaloid found in the root of the plant <i>Tabernanthe iboga</i> .  |
| <b>Objectives</b>   | <ol style="list-style-type: none"> <li>1. To investigate the short term effects of Ibogaine on opioid withdrawal during a one week detoxification period (in-patient phase).</li> <li>2. To investigate the safety of Ibogaine during acute in-hospital opioid withdrawal and during an 8 week post treatment evaluation.</li> <li>3. To investigate the long term effects on craving and substance use of opiates during a two month (8 week) follow-up period (out-patient phase).</li> <li>4. Secondary questions concern possible somatic and psychological effects of Ibogaine, and possible predictive factors for response to Ibogaine and evaluation of pharmacokinetics.</li> </ol>  |
|                     |   |
| <b>Study Design</b> | <p>Following pre-admission intake, the study consists of two phases, conducted in three separate segments:</p> <ol style="list-style-type: none"> <li>1. <u>The first phase, the in-patient phase</u>, consists of 6-10 days hospitalization. After a short in-patient stabilization period including comprehensive medical and psychiatric assessment, four opioid-dependent volunteers (Subject Group A) will be administered a single therapeutic dose of Ibogaine. Following the administration of the Ibogaine, time is allotted for complete medical and psychological recovery. Post-treatment consists of observation and extensive medical and neuro-behavioral evaluations.</li> <li>2. <u>The second phase, the out-patient follow-up phase</u>: Upon hospital discharge, a series of 8 weekly follow-up visits will be scheduled in order to evaluate the long term effects of this treatment modality and to assist the patient to enter and conduct a drug-free style of life. During this phase, conventional medical, psychiatric, psychological and social services will be provided.</li> <li>3. For safety reasons, the Ibogaine dose will be escalating. Therefore, only after the first four patients have completed the follow-up phase, four additional patients (Subject Group B) will be enrolled to the study and the therapeutic dose will be escalated.</li> <li>4. After Subject Group B has completed the follow-up phase, an additional four patients (Subject Group C) will be enrolled in the study and the therapeutic dose will be further escalated.</li> </ol> |

|                                  |   |
|----------------------------------|---|
| <b>Sample Size</b>               | 12 active opioid-dependent subjects, currently seeking treatment will form three Subject Groups: A, B, and C.   |
| <b>Study Drug Administration</b> | <p>After three days of stabilization, Subject Group A, consisting of four subjects, will receive a single therapeutic dose of Ibogaine per os concomitantly with anti-nauseant medication.</p> <p>Eight weeks later, upon completion of the follow-up period for Subject Group A, Subject Group B will be admitted, stabilized, and administered a single therapeutic dose of Ibogaine, escalated in accordance with the Protocol.</p> <p>Upon completion of the follow-up period for Subject Group B, Subject Group C will be admitted, stabilized, and administered a single therapeutic dose of Ibogaine, escalated in accordance with the Protocol.</p> |
| <b>Efficacy Measurements</b>     | Evaluation of study drug in the treatment of opiate withdrawal signs and evaluation for drug use and craving as compared to baseline.   |
| <b>Safety Measurements</b>       | Medical and psychological well-being as compared to baseline.   |
| <b>Duration of the Study</b>     | 2 days of stabilization; 1 day of active treatment; 3-6 day recovery period; followed by 8 weeks of out-patient evaluation.   |