Sample Consent Form for a Non-Clinical Study

1. Study Title: Association between Drug Usage and Migraine Headaches: Effects of Migraine Headaches on Attention

2. The purpose of this research project is to determine whether there is an association between controlled drug use and migraine headaches and whether migraine headaches alter one's ability to concentrate. The study will take place over a period of 6 months. Your expected time in the study will be 3 months. The study will be conducted in two phases. In the first phase, subjects will spend approximately 20 minutes completing two questionnaires, one about migraine headache symptoms; and the other, about past or current psychological diagnoses and alcohol and drug use. In the second phase, subjects will spend approximately two hours completing 8 tests of attention. My participation will be audio or video recorded.

3. Risks: The only study risk is the inadvertent release of sensitive information found in the second questionnaire. However, every effort will be made to maintain the confidentiality of your study records. Files will be kept in secure cabinets to which only the investigator has access. If your project could elicit emotional or psychological issues in the subjects, you need to insert contact information for relevant support services in this consent. When possible, the listings need to be local and national. Please contact the IRB office if you have questions.

4. Benefits: Subjects will be paid $10 to participate in the study. Additionally, the study may yield valuable information about migraine headaches.

5. Alternatives (if applicable): It is specified whether there are proven, established treatment options available that may be advantageous to the subject (in lieu of the study treatment).

6. Investigators: The following investigators are available for questions about this study, M-F, 8:00 a.m. - 4:30p.m., Dr. John Doe, 578-0001; Dr. Jane Smith, 578-1002

7. Performance Site: Louisiana State University and Agricultural and Mechanical College

8. Number of subjects: 50

9. Inclusion Criteria: Individuals between the ages of 18 and 65 who do not report psychological or neurological conditions. To participate in this study you must meet the requirements of both the inclusion and exclusion criteria.

10. Exclusion

be published, but no names or identifying information
Subject identity will remain confidential unless

13. Signatures:
    The study has been disc