

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 Criteria: Individuals under age 18 or over age 65. If you have psychological or neurological conditions.
11. Right to Refuse: Subjects may choose not to participate or to withdraw from the study at any time without penalty or loss of any benefit to which they might otherwise be entitled.
12. Privacy: Results of the study may be published, but no names or identifying information will be included in the publication. Subject identity will remain confidential unless disclosure is required by law.

13. Signatures:

The study has been discussed with me and all my questions have been answered. I may direct additional questions regarding study specifics to the investigators. For injury or illness, call your physician, or the Student Health Center if you are an LSU student. If I have questions about subjects' rights or other concerns, I can contact Dennis Landin, Institutional Review Board, (225) 578-8692, irb@lsu.edu, or www.lsu.edu/research. I agree to participate in the study described above and acknowledge the investigator's obligation to provide me with a signed copy of this consent form.

Subject Signature: _____ Date: _____

The study subject has indicated to me that he/she is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above, the subject has agreed to participate.

Signature of Reader: _____ Date: _____

14. For research involving the collection of identifiable private information or identifiable biospecimens one of the following must be listed on the consent form:

Identifiers might be removed from the identifiable private information or identifiable biospecimens. After removal, the information or biospecimens may be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

Yes, I give permission _____
Signature

No, I do not give permission _____
Signature

OR

Your information or biospecimens collected as part of the research, even if identifiers are removed, may be used or distributed for future research.

Yes, I give permission _____
Signature

No, I do not give permission _____
Signature