Template for a Certificate of Confidentiality Application

1. **Name and address of applicant and research institution**

   Jane Doe, Professor
   Department of Kinesiology
   Louisiana State University
   Baton Rouge, LA 70803
   Phone: 225-578-0000
   Email: janedoe@lsu.edu

2. **Sites where research will be conducted and a brief description of the facilities available for the conduct of the research**

   The study will be conducted in the Kinesiology Department in the Long Fieldhouse at Louisiana State University. Participants will complete questionnaires through a secure online system (Qualtrics). The attention tests and data management will occur in Dr. Doe's facility in the Kinesiology Department. Dr. Doe will oversee data collection and management of the data.

3. **Title of the research project**

   Association between Drug Usage and Migraine Headaches: Effects of Migraine Headaches on Attention

4. **Source and number of the supporting grant**

   If you do not have a grant, state not applicable

5. **IRB approval of the research project**

   This research project is approved by the Louisiana State University Institutional Review Board and is IRB# XXXX.

6. **Documentation of the IRB approval**

   IRB approval letter is attached.

7. **Documentation of IRB qualifications**

   List the FWA number found on our regular application form.

8. **Contact information of the applicant as well as name and title of other key personnel**

   Name/Title: Jane Doe, Professor
   Mailing Address: Department of Kinesiology
   Louisiana State University
   Baton Rouge, LA 70803

Phone: 225-578-0000
Email: janedoe@lsu.edu

Name: John Doe, Graduate Student
Mailing Address: Department of Kinesiology
Louisiana State University
Baton Rouge, LA 70803
Phone: 225-578-0000
Email: johndoe@lsu.edu

9. **Beginning and expected end date of the project**
   The project aims to begin on 1/2/2020 and is expected to end on 5/30/2020.

10. **Concise description of project aims and research methods**
    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 eight tests of attention.

11. **Description of means used to protect subject's identities**
    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.

12. **Reasons for requesting a Certificate of Confidentiality**
    We are collecting identifying information on participants for this study. The information includes participant's history on use of controlled drugs and substance use.

13. **Informed consent forms for human subjects as approved by the IRB**
    The consent form is attached.

14. **Research not funded by NIH in which drugs will be administered to human subjects**
    State not applicable if it does not apply.

15. **Drug Enforcement Administration Certificate of Registration (BND form 223)**
    State not applicable if it does not apply.

16. **Compliance with State reporting laws on communicable diseases**
    State not applicable if it does not apply.

17. Assurances

This institution agrees to use the Certificate of Confidentiality to protect against disclosure of personally identifiable information and to support and defend the authority of the Certificate. Specifically, any investigator or institution conducting research protected by a Certificate of Confidentiality SHALL NOT, without the specific consent of the individual to who the information pertains:

• Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research; or

• Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure of protected information is permitted only when:

• Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;

• Made with the consent of the individual to whom the information, document, or biospecimen pertain, including disclosure necessary for an individual's medical treatment; or

• Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research

The institution understands that research information protected by a Certificate of Confidentiality and all copies thereof are protected in perpetuity and are subject to the protections and the disclosure requirements noted above.

The institution understands that identifiable, sensitive information protected by the Certificate of Confidentiality and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used for any purpose in any action, suite, or other judicial, legislative, or administrative proceeding.

The institution and personnel involved in the conduct of the research will comply with the informed consent requirements of the applicable Federal regulations, including 45 CFR Part 46.

This Certificate of Confidentiality will not be represented as an endorsement of the project by the HHS or NIH or used to coerce individuals to participate in the research project.

For studies in which informed consent is sought, subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate. Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.

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Principal Investigator PI Name Title Institution	Institutional Official Stephen Beck, Ph.D. Associate Vice President Research and Economic Development Louisiana State University
Date:	Date: