

Sample Consent Form for a Clinical Study

1. Study Title: Heart Disease Risk Factors
2. Performance Site: X General Hospital
3. Investigators: The investigator listed below is available to answer questions about the research, M-F, 8:00 a.m. - 4:00 p.m.
Dr. Jane Doe
578-0000
4. Purpose of the Study: The purpose of this research project is to identify risk factors for heart disease associated with the presence of fatty compounds in the blood.
5. Subject Inclusion: Individuals, ages 18-50, who have suffered a heart attack and are currently hospitalized for treatment of this condition. To participate in this study you must meet the requirements of both the inclusion and exclusion criteria.
6. Number of Subjects: 125
7. Study Procedures: Each subject will have approximately 2 additional tablespoons of blood drawn from his/her arm at the same time blood is being drawn for tests associated with his/her treatment for heart attack. I will be audio or video recorded when discussions arise.
8. Benefits: There are no direct benefits to the subjects. However, information gained from the study may provide early identification of at-risk individuals to whom prevention efforts can be directed.
9. Risks/Discomforts: There is slight discomfort and a small chance of faintness associated with a needle stick; there is also a slight possibility of bruising, bleeding, and inflammation/infection at the site of needle insertion. These risks/discomforts are minimized by the collection of the blood by a registered medical technologist using proper procedure.

In any event, the collection of 2 extra tablespoons of blood does not constitute additional risk to the subject since blood is already being drawn for treatment, rather than study, purposes.
10. Injury/Illness: In the unlikely event of injury or medical illness resulting from the drawing of 2 additional tablespoons of blood, contact NAME, TITLE, PHONE #. You will be referred for treatment, but the expense of medical treatment will be your responsibility. No compensation is available in case of study-related illness or injury.
11. Right to Refuse: Subjects may choose not to participate or to withdraw from the study at any time with no jeopardy to their treatment by their respective doctors or other penalty at the present time or in the future.
12. Privacy: The LSU Institutional Review Board (which oversees university research with human subjects) and SPONSOR NAME (if applicable) may inspect and/or copy the study records.

Results of the study may be published, but no names or identifying information will be included in the publication.

Other than as set forth above, subject identity will remain confidential unless disclosure is legally compelled.

13. Financial Information: There is no cost to the subjects, nor is there any compensation for participating in the study.

14. 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, www.lsu.edu/irb. I agree to participate in the study described above and acknowledge the investigator's obligation to provide me with a signed copy of the 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: _____