

Sample Consent Form for a Clinical Study

1. Study Title: Heart Disease Risk Factors
2. The purpose of this research project is to identify risk factors for heart disease associated with the presence of fatty compounds in the blood. The study will take place over a period of 6 months. Your expected time in the study will be 3 months. 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.
3. 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.

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: 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.
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. Injury/Illness: In the unlikely event of injury or medical illness resulting from the drawing of 2 additional tablespoons of blood, contact NAME, TITLE, and 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.
7. 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 and Dr. John Doe, Psychology Dept, LSU, 504-578-0000.
8. Performance Site: X General Hospital
9. Number of Subjects: 125
10. Inclusion Criteria: Individuals aged 18-50. You must 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.
11. Exclusion Criteria: Individuals under age 18 and over age 50. If you did not suffer a heart attack and are not currently in the hospital for this condition.

12. 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.
13. Financial Information: There is no cost to the subjects, nor is there any compensation for participating in the study.
14. 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. Please be aware that data collected in this Federally funded project will be posted to the ClinicalTrials.gov website and available to the public. All identifiers will be removed from the data prior to deposit at the website.
15. 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.
16. 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 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: _____

17. 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