# Guide to:
# Informed Consent

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# Overview

Informed consent must be sought from each prospective subject or the subject's legally authorized representative.

A consent form is used to document the information provided to a subject to gain his/her agreement to participate in a study. It is the culmination of a process in which the investigator explains the study thoroughly and answers any questions a subject may have about it.

When the subject is a minor (less than 18 years of age), parental permission must be obtained for the child to participate in the study; and the minor must assent, i.e., agree to participate in the study. Research involving more than minimal risk and no prospect of direct benefit to individual subjects requires the permission of both parents, unless one is reasonably unavailable or one has legal custody. Parental permission is documented in a form analogous to a consent form, differing in that the parent is agreeing to allow his/her child to participate, rather than agreeing to personally participate. If the minor is aged 6-18, an assent form documenting in age-appropriate language, the minor's agreement to participate, is usually required.

The Code of Federal Regulations (45 CFR 46) mandates the types of information that must be included in a consent form. In addition to containing all the federally-mandated elements of consent, to be acceptable, the consent form must be: (1) clear, using simple nontechnical language that an individual reading on the sixth grade level can comprehend; (2) comprehensive, furnishing all the elements in sufficient detail that potential subjects can understand what is required of them and weigh the benefits of participating against the risks of participating; (3) succinct, 3 pages maximum; and (4) stand-alone, not part of a letter requesting the individual to participate.

A copy of the consent form must be given to each research subject and a signed copy retained in the investigator's record for 3 years after completion of the study.

# Consent Form Checklist

The Consent Form Checklist is designed to ensure you have included all the required elements of informed consent, using appropriate language. This should help maximize the probability of receiving approval promptly, since deficiencies must be addressed before approval can be granted.

**For #1-12 below, indicate by yes or no whether each element is addressed in your consent form. (a "no" answer indicates a consent form deficiency which must be remedied before the IRB application can be approved.)**

Y/N (Unless another appropriate response alternative is requested)

___ 1. Study Title: Name of the study.

___ 2. Performance Sites: Where the study will be conducted.

___ 3. Contacts: The names and telephone numbers of Investigators and hours available.

___ 4. Purpose of the Study: It is stated in lay language that the study is research and, what the investigator wishes to accomplish.

5. Subjects:

___ A. Inclusion Criteria All criteria for participation in the study are specified. (Examples: >18 years old, left or right-handed, diagnosed with a specified condition; Subject pool, e.g. psychology undergraduate students, senior citizens, etc.)

___ (Or NA)B. Exclusion Criteria Specify any subset of those meeting the inclusion criteria to be excluded from the study. (If none, indicate N/A & omit from Consent Form.)

___ 6. Number of Subjects: Maximum number of subjects anticipated including controls) if relevant.

___ 7. Study Procedures: A succinct, complete, specific nontechnical explanation (of what the subject will experience or be required to do, is provided (e.g. 1 tsp. blood, rather than 5 cc. blood). If questionnaires are used, a description of types of questions - particularly if of a personal or sensitive nature is provided. Procedures which are experimental, either in the clinical sense, where a trial treatment is being studied; or any untried procedure which might hold risk for the subject is explained. The number and duration of sessions, and the overall time commitment are stated.

A. If blood is to be withdrawn, the following is provided:

___ (1) number of times, amount, period of time covered, minimal risk of bruising, inflammation of vein and infection;
___ (2) qualifications of personnel collecting blood. (Comparable information for other procedures, invasive or not)

___ B. If investigational drugs or devices are to be used, or if approved drugs or devices are to be used in a manner for which they have not been approved, the consent form identifies the drugs or devices as experimental.

___ 8. Benefits: Study benefits to subjects or to others (societal benefits) which may reasonably be expected are stated.

___ 9. Risks/Discomforts: You must, at a minimum, state there is no known risk! Any potential for physical harm (e.g., risks associated with having blood drawn); potential for psychological harm (eg: distress at being asked sensitive questions of a very personal nature); and potential for social harm (e.g., collection of information such as drug or alcohol use or abuse, which if inadvertently released, could be damaging). It is helpful to include measures to reduce risk (e.g. use of trained personnel, safety procedures, measures to assure confidentiality).

___ 10. Right to Refuse: It is stated that participation in the study is voluntary and that subjects may change their mind and withdraw from the study at any time without penalty or loss of any benefit to which they may otherwise be entitled.

___ 11. Privacy: It is specified whether the study is Anonymous or Confidential (An anonymous study is one in which the data cannot be linked to the identity of the subject directly or indirectly – either because the name/identity of the subject is never obtained by the investigator, or because there is no code linking data to the subject's identity.) If the study is not anonymous, i.e., if there is a code linking data to identity, describe the extent, if any, to which confidentiality of records identifying the subject will be maintained. Confidentiality cannot be absolute: always state 'data will be kept confidential unless release is legally compelled'.

____ 12. Financial Information: Any compensation for participating and any uncompensated costs incurred by subjects are specified. (State when incentives will be delivered).

**Numbers 13-16 must be included in a consent form when a subject enters an experimental medical or behavioral treatment program. To explore the potential to remedy a condition from which he/she suffers.**

___ Check here if not applicable and skip to #17. (otherwise, answer each question with yes or no. "No" indicates a consent form deficiency Which must be remedied before the IRB application can be approved.)

___ 13. Alternatives: It is specified whether there are proven, established treatment options available that may be advantageous to the subject (in lieu of the study treatment).

___ 14. Unforeseeable Risks: It is specified that the treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

15. Study-associated injury or illness:

___ A. Any compensation or medical care which will be arranged for or provided by the investigators is described

___ B. Subjects are informed what to do and whom they are to notify in the event of a study-related illness or injury.

___ 16. New Findings: Significant new findings developed from the study data or independent sources during the course of the research which may relate to the subjects' willingness to continue participation (e.g., adverse response to the treatment) will be explained to the subjects.

**Numbers 17-18 must be included in a consent form when a subject's failure to complete a study will deprive the subject of benefit (including compensation) or expose the subject to risk.**

___ Check here if not applicable and skip to #19. (otherwise, answer each question with yes or no. "no" indicates a consent form deficiency Which must be remedied before the IRB application can be approved.)

___ 17. Withdrawal: Specify the consequences of a subject's unilateral decision to withdraw from the research, and explain the procedures for orderly termination of participation.

___ 18. Removal: List/explain the conditions or situations under which the investigator will remove the individual from the study without his/her consent.

**Number 19 is REQUIRED FOR ALL STUDIES:**

___ 19. 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. If I have questions about subjects' rights or other concerns, I can contact Robert C. Mathews, Chairman, LSU 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 researchers' obligation to provide me with a copy of this consent form if signed by me.'

Subject Signature:_____ Date:_____

___ 20. Illiterate subjects (When ANY subjects are likely to be illiterate, the "reader statement" and signature line below are included.)

'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:_____

**Check #21-23 below to be sure your consent form is correct:**

___ 21. Is the consent form written for the 6th grade reading level in nontechnical language which can be understood by the subjects?

___ 22. Is the consent form free of any exculpatory language through which the participant is made to waive, or appears to be made to waive any legal rights, including any release of the investigator, sponsor, institution or its agents from liability for negligence? (Note: the consent form is not a contract.)

___ 23. Are minors (individuals who have not reached the legal age of consent, age 18 in LA) study subjects? If so, is provision made for:

___ (A) securing and documenting the assent of the minors?

___ (B) securing and documenting parental permission?

Note: Signature of the Investigator is not required on the consent form, and leads to the false impression the Consent Form is a contract.

# Guide to Assent for Minors

Federal regulations require a number of special protections for minors (in Louisiana, persons under the age of 18).

45 CFR 46.408 states "the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. ... the IRB shall take into account the ages, maturity, and psychological state of the children involved." (The LSU IRB is likely to also take into account the nature of the study.)

Assent is a process in which the research is adequately explained, questions fully answered, and agreement to participate, if granted, is documented. In obtaining a minor's assent, at a minimum, the subject must have explained to him or her orally in age-appropriate terms what will happen to the individual, why it is being done (e.g., "to find out..."), any risks or discomfort expected, and any benefits to the individual or to others. Refusal to assent must be honored, no matter how irrational it may appear to be. Mere absence of dissent may not be regarded as assent.

LSU IRB policy regarding assent:

1. Assent will generally be required of children aged 6-18. However, the lower age limit may be modified in special circumstances.

2. It is recommended that assent be obtained in the presence of the parent when possible, unless there is evidence the parent will be inappropriately coercive of the child entering the study.

3. To document assent, a separate instrument - in addition to the parent or guardian's permission form - is usually required. The assent form should reflect in suitably simple terms what information has been conveyed to the minor subject in order to secure his/her agreement to participate in the study. However, in certain FAMILY studies, if it seems appropriate that the decision to participate be made jointly by parent(s) and child, parental permission and child's assent may be documented in the same form.

4. The assent form should record the age of the child and the date of signatures.

5. The assent form should be signed by a witness to the assent procedure (may be the parent/guardian or a third party). When a witness is used to assist in documenting assent, the witness should be present to attest to the entire consent process, not just to the child's final acquiescence. The child should sign the assent form if judged to be able to understand that signature represents a REVOCABLE agreement to participate in the research. Normally the child's signature would not be requested below age 8.

6. Original signed assent and parental permission documents must be kept in the investigator's records for at least 3 years after termination of the study.

Finally, the investigator(s) must pay attention to the fact that a young child may be unable to verbalize dissent or a wish to withdraw from the study, and so must be alert and responsive to the child's non-verbal cues. For instance, if a child physically resists a procedure, resistance should be considered an indication of dissent, and the investigator has an obligation to desist, unless he/she can establish that the child is willing to continue in spite of the evident discomfort. These considerations become imperative if there is no overriding benefit to the individual child.

In longitudinal studies, it may be appropriate to ask the subject to reaffirm assent at intervals.

# 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.

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.

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. If I have questions about subjects' rights or other concerns, I can contact Robert C. Mathews, 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:_____

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

3. 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

4. Purpose of the Study: 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.

5. Subject Inclusion: Individuals between the ages of 18 and 65 who do not report psychological or neurological conditions.

6. Number of subjects: 50

7. Study Procedures: 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.

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

9. 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.

10. 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.

11. 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.

12. 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. If I have questions about subjects' rights or other concerns, I can contact Robert C. Mathews, 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 this consent form.

Subject Signature:_____ Date:_____

# Sample Parental Permission Form

Project Title: Comparison of Intervention Strategies for Addressing Inappropriate Classroom Behavior

Performance Site: X Elementary School

Investigators: The following investigator is available for questions,
M-F, 8:00 a.m.-4:30 p.m.
Dr. Jane Doe
Psychology Dept., LSU
(504) 578-0000

Purpose of the Study: The purpose of this research project is to develop effective strategies for teachers to use with students exhibiting disruptive classroom behavior.

Inclusion Criteria: Children 6-9 years of age whose teachers have referred them for disruptive classroom behavior.

Exclusion Criteria: Children who do not meet the age requirements or who have not been referred for disruptive behavior, or whose teachers do not use time-out in their classrooms.

Description of the Study: Over a period of one month, 2-3 days per week, the investigator, posing as a teacher's aide, will observe subjects' general classroom behavior, assign specific tasks to the subjects, and will use three intervention techniques with the subjects: positive attention, reprimand, and time-out.

In the positive attention technique, the "teacher's aide" will provide the subject with positive attention, regardless of the occurrence of problem/disruptive behavior. In the reprimand technique, the "teacher's aide" will respond to each instance of disruptive behavior with a neutral reminder (e.g., you need to be working). In the time out technique, for each instance of problem behavior, the "teacher's aide" will remove the subject's work and turn his/her desk away from the classroom activities and other students for 30 seconds. At the end of 30 seconds, the investigator will turn the subject's desk back to the original position and gesture for the subject to return to work.

Benefits: Subjects will have the opportunity to earn "awards" for performance of tasks assigned by the "teacher's aide." The study may identify intervention strategies which will help the subjects to minimize their disruptive classroom behaviors. The benefit to other students and the teacher is identification of techniques to help provide a classroom environment more conducive to learning.

Risks: There are no known risks.

Right to Refuse: Participation is voluntary, and a child will become part of the study only if both child and parent agree to the child's participation. At any time, either the subject may withdraw from the study or the subject's parent may withdraw the subject from the study without penalty or loss of any benefit to which they might otherwise be entitled.

Privacy: The school records of participants in this study may be reviewed by investigators. Results of the study may be published, but no names or identifying information will be included for publication. Subject identity will remain confidential unless disclosure is required by law.

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

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 investigator. If I have questions about subjects' rights or other concerns, I can contact Robert C. Mathews, Chairman, Institutional Review Board, (225) 578-8692, irb@lsu.edu, www.lsu.edu/irb. I will allow my child to participate in the study described above and acknowledge the investigator's obligation to provide me with a signed copy of this consent form.

Parent's Signature:_____ Date:_____

The parent/guardian has indicated to me that he/she is unable to read. I certify that I have read this consent from to the parent/guardian and explained that by completing the signature line above he/she has given permission for the child to participate in the study.

Signature of Reader:_____ Date:_____

# Sample Child Assent Form

I,_____, agree to be in a study to find ways to help children act better in school. I will have to do special school work for the teacher's aide in my classroom. Sometimes I will do math and reading. Other times I may get to play a game with another student. I have to follow all the classroom rules, even when I am working with the teacher's aide. I can decide to stop being in the study at any time without getting in trouble.

Child's Signature:_____ Age:_____ Date:_____

Witness* _____ Date:_____

* (N.B. Witness must be present for the assent process, not just the signature by the minor.)

# Sample Consent Guide for Mail & Telephone Surveys

The consent process for mail surveys can be handled in more than one way. In the first way, the PI sends the subject a letter requesting participation; the letter is accompanied by a conventional consent form which the individual signs and returns with his/her survey. If the study is to be anonymous, the consent form is separated from the survey immediately upon opening the package. In the second way, the PI provides on the face page of the survey the information generally found in the consent form; also included there is a statement that by answering the questions and returning the survey, the subject is providing and documenting his/her consent. The PI annotates the survey to the effect informed consent was received.

For telephone surveys, the interviewer reads from a "script"* written on the survey document. The script contains a comprehensive, though succinct, description of the study and includes the relevant elements of informed consent - in narrative form. The interviewer solicits any questions the potential subject may have and answers them. The interviewer directly asks the person if he/she agrees to participate in the survey. Finally, the PI documents on a data sheet: (1) that the script was read; (2) the individual was offered the opportunity to ask questions; and (3) the individual agreed or declined to participate in the study.

IRB contact information by me listed on mail surveys and read on telephone surveys. Questions about subjects' rights or other concerns, contact Robert C. Mathews, Chairman, Institutional Review Board, (225) 578-8692, irb@lsu.edu, www.lsu.edu/irb.

* N.B. (The script must be submitted to the IRB for approval prior to its use in the study.)