

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. Purpose of the Study and Study Procedures: Stated in lay language that the study is research, and what the investigator wishes to accomplish. 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. If parts of the study will be audio or video recorded, that must be stated in the consent.

A. If blood is to be withdrawn, the following is provided: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

___ 3. Risks/Discomforts: You must, at a minimum, state there is no known risk! State 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).

___ 4. Benefits: Study benefits to subjects or to others (societal benefits) which may reasonably be expected are stated.

- ___ 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. Contacts: The names and telephone numbers of all investigators and hours available.
- ___ 7. Performance Sites: Where the study will be conducted.
- ___ 8. Number of Subjects: Maximum number of subjects anticipated including controls if relevant.
- ___ 9. 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.
- ___ B. Exclusion Criteria: Specify any subset of those meeting the inclusion criteria to be excluded from the study.
- ___ 10. Privacy: Specify 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.”
- ___ 11. Financial Information: Any compensation for participating and any uncompensated costs incurred by subjects are specified. State when incentives will be delivered.
- ___ 12. Right to Refuse: State participation in the study is voluntary and 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.

Numbers 13-15 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 #16. 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. Unforeseeable Risks: Specify 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.
- ___ 14. 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.
- ___ 15. New Findings: Significant new findings developed from the study data or independent sources during the course of the research which may relate to the subject's willingness to continue participation (e.g., adverse response to the treatment) will be explained to the subjects.

Numbers 16-17 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 #18. 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.
- ___ 16. Withdrawal: Specify the consequences of a subject's unilateral decision to withdraw from the research, and explain the procedures for orderly termination of participation.
- ___ 17. Removal: List/explain the conditions or situations under which the investigator will remove the individual from the study without his/her consent.

Number 18 is REQUIRED FOR ALL STUDIES:

- ___ 18. 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 subject's rights or other concerns, I can contact Dennis Landin, Chairman, LSU 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 researcher's obligation to provide me with a copy of this consent form if signed by me."

Subject Signature: _____ Date: _____

- ___ 19. 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 read this consent form to the subject and explained by completing the signature line above, the subject agreed to participate."

Signature of Reader: _____ Date: _____

- ____ 20. **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

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.

Please contact us if you have questions about this guide.



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