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## **GUIDANCE TO AUTHORS: INFORMED CONSENT DOCUMENT**

This document provides guidance on the required and additional elements of an Informed Consent Document as well as additional information for consideration.

- (a) **That the trial involves research**, that the research is approved by an IRB, and an explanation of the purpose of the IRB.
- (b) **The purpose of the trial**: indicate that the purpose of the trial is to assess or evaluate whether the test article is safe and, where appropriate, effective in the treatment of the disease or condition.
- (c) **The trial treatment(s) and the probability for random assignment to each treatment**: identify the test article by name and indicate that if it or any procedure is investigational or experimental. If the test article is approved, indicate what aspect of the study is investigational or experimental. Identify the comparator by name. If placebo is to be used as the comparator or at any time during the study, state this clearly and explain the term "placebo" (e.g., "a dummy treatment that contains no active ingredients"). Give the dosage of the test article/comparator and method of administration. Indicate how treatment will be assigned (whether randomized, e.g., "like flipping a coin" or "pre-selected by a computer") and give the chances for assignment to each treatment (e.g., "50% chance" or "one in three"). Indicate whether treatment is blinded ("neither you nor your doctor will know which treatment you will receive") or open label.
- (d) **The trial procedures to be followed, including all invasive procedures**: describe succinctly and in chronological order those procedures that are distinctly a part of the trial. It is not necessary to describe procedures that are part of routine care. Specify the study procedures to be performed, e.g., physical examination, blood samples, urine specimens, x-rays, CAT scans, pregnancy tests, etc. If blood is to be drawn for clinical labs and/or pharmacological samples, the participant should be informed of the amount of blood that will be taken. This should be explained in lay terminology, e.g., teaspoons instead of cc. If blood is to be tested for HIV or other infectious disease, this must be specifically stated. If the participant will be exposed to radiation, state the amount in rads or grays (Gy).
- (e) **The participant's responsibilities**: state how often the participant will be expected to visit the clinic and approximately how much time visits and procedures require. State the participant's obligation to use an approved form of birth control during study. Indicate any lifestyle or dietary restrictions and whether the participant will be expected to complete a patient diary or other questionnaire. State that the participant will be expected to return unused test article (including empty containers) at each visit. Indicate that the participant must inform the trial physician of any sicknesses, adverse events, changes in medication, etc. during the trial.
- (f) **The aspects of the trial that are experimental**: this may be addressed together with item (d).
- (g) **The reasonably foreseeable risks or inconveniences** to the participant and, when applicable, to any embryo, fetus or nursing infant: describe the known risks, adverse events, discomforts and inconveniences of the test article and the comparator. Indicate risks of inducing malignancy if pertinent. Describe also any risks associated with investigational procedures. Use lay terminology when discussing all risks and discomforts. Explain that there may be other adverse events to the participant (or embryo or fetus) of which there is no current knowledge. (Do not refer to the test article as "safe" or "effective", as these terms may only be used after regulatory approval. Even for approved products, it is preferable to refer to the test article's "good safety profile" than to state that

the test article is “safe”). State the possibility that the study treatment might damage an unborn child, and for this reason, women who are pregnant or plan to become pregnant must not participate in the trial. State that women of childbearing potential must use an acceptable method of birth control throughout the study. List the acceptable forms of birth control from the study protocol. Provide where appropriate a statement to alert male participants to the risk of damage to sperm, and consequently, of a damaged fetus.

- (h) **The reasonably expected benefits.** When there is no intended clinical benefit to the participant, the participant should be made aware of this. List all potential benefits to the participant and/or medical science. Present any potential benefit(s) in a balanced manner and do not overstate. Where there is no direct benefit to the participant, a standard statement may be used such as, “You may or may not benefit personally from participating in this study. However, by serving as a participant, you may contribute new information which may benefit patients in the future.”
- (i) **The alternative procedure(s) or course(s) of treatment** that may be available to the participant: describe alternative non-research procedures or treatments available and their important potential benefits and risks. Avoid stating or implying that there are no alternatives.
- (j) **The compensation and/or treatment available to the participant** in the event of trial-related injury: if the study is funded by a pharmaceutical or medical device company or private organization, the compensation statement from that source regarding provision of medical treatment or compensation in the event of complications as a result of the study drug, study device, or study procedures should be added. Describe how the participant will be compensated for any injury suffered as a result of his/her participation in the trial. If there is no treatment or compensation offered, state this explicitly and add, “However, you have not waived your legal rights by signing this form.” If the project is being funded by any Department of Health and Human Services agency include the following paragraph, “It is not the policy of the U.S. Department of Health and Human Services, or any federal agency funding the research project in which you are participating to compensate or provide medical treatment for human participants in the event the research results in physical injury.”
- (k) **The anticipated prorated payment,** if any, for participating in the trial: if the participant will receive compensation for his/her involvement, indicate the exact amount and give a breakdown by visit and/or procedure. Indicate how the compensation will be adjusted if the participant withdraws early.
- (l) **The anticipated expenses, if any, for participating in the trial:** if there are no direct costs for the participant for participating in the trial, state this explicitly. Participants may incur indirect costs for travel, loss of income, etc., as a result of participation in the trial and these costs may or may not be reimbursed. Therefore, avoid stating that participation in the study will not result in any additional costs to the participant.
- (m) **That participation in the trial is voluntary** and that the participant may refuse to participate or withdraw from the trial at any time, without penalty or loss of benefits to which the participant is otherwise entitled: emphasize that that participant’s participation is strictly voluntary and that the participant may discontinue his/her participation in the study at any time. Add a statement that if the participant wishes to discontinue, he/she should contact the trial physician for advice on test article discontinuation. The participant may also be asked to undergo physical examination or laboratory tests as part of the discontinuation procedures. List the *consequences* (i.e. medical or psychological, financial if any) of the participant’s decision to withdraw from the research
- (n) **That the monitor(s), the auditor(s),** the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the participant’s original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant’s legally acceptable representative is authorizing such access. For FDA regulated

research. A statement that notes the possibility that the FDA might inspect the records. A statement that regulatory authorities may inspect the record does not meet this requirement

- (o) **That records identifying the participant will be kept confidential** and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the participant's identity will remain confidential: provide a statement such as, "Neither your name nor anything that could identify you will appear in any report or record of the study".
- (p) **That if new information becomes available** it will be made known to the participant or his/her legally authorized representative will be informed in a timely manner if it may be relevant to the participant's willingness to continue participation in the trial.
- (q) **The person(s) to contact for further information** regarding the trial and the rights of trial participants, and whom to contact in the event of trial-related injury: make provision for names of individuals and contact details. For information regarding the trial and for trial-related injuries, this individual should be the investigator or a member of the investigational staff. For rights of trial participants, this may be an independent person or third party or a patient organization.
- (r) **The foreseeable circumstances and/or reasons under which participation in the trial may be terminated:** clarify the circumstances under which participation may be terminated without the participant's consent (e.g., investigator discretion, client company terminating trial, participant non-cooperativeness, etc.)
- (s) **The expected duration of participation in the trial:** indicate the length of time the participant will be involved with this study.
- (t) **The approximate number of participants involved in the trial:** indicate the expected total number of participants in the trial.

#### **GENERAL COMMENTS:**

1. **The written information and the informed consent document identify the study:** quote the title of the study. If the title contains very scientific or technical terms, provide an equivalent in lay terminology.
2. **The written informed consent document makes provision for the participant or the participant's legally acceptable representative, and the person who conducted the informed consent discussion to sign and personally date:** provide space for the printed name of the participant to be entered. Provide space for the participant's signature with date, and/or the signature with date of the participant's legally acceptable representative. Solicit the relationship of the representative to the participant. Provide space for the trial physician/delegate who conducted the discussion to sign and personally date the form. Local regulations may require that the discussion be witnessed, and in this case, provide space for the witness to sign and personally date the form as well.
3. **The information concerning the trial does not contain any language that causes the participant or the participant's legally acceptable representative to waive or to appear to waive any legal rights:** do not use any statement which would imply that the participant is participating at his/her own risk and/or agrees to waive any compensation for injury.
4. **The information concerning the trial does not contain any language that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence:** do not use any statement which would imply that the participant is participating at his/her own risk and/or agrees to hold the parties mentioned blameless.

5. **The language used in the information about the trial, including the written informed consent document is understandable and as non-technical as is practical:** use simple, non-technical terms which can be easily understood by a lay person. Use short words, sentences and paragraphs. Avoid the use of language that could be perceived as coercing or pressuring the participant to participate, such as, “your doctor would be grateful if you would consent to participate in this study” or “thank you in advance for participating in this study.”
6. **The written information and the informed consent document identify the version of the document:** identify the version by means of a version date or a version number (e.g., 15FEB01 or version 3 or 15FEB01 version 3). Ensure the version date/number is revised any time a change—even a minor change such as correction of grammatical or spelling errors—is made in the document.
7. **The informed consent document contains a footer:** identify the protocol, usually with a protocol number, version (date and/or number). Paginate the document, indicating current page out of the total number of pages (e.g., 2 of 3 or 2/3). Although it is not required, it is recommended that a participant initial and date line be provided on each page of the consent form. As the participant reads and understands the consent form, each page should be initialed and dated to document this.
8. **The informed consent document is easy to read:** use a plain font and avoid the use of italics. Avoid the use of upper case letters, except in headings. Select a font size that is suitable for the intended reader (e.g., large size for elderly participants or those with impaired vision).
9. **The informed consent document should address the sponsorship/funding of the trial.** A statement should be included identifying the sponsor and who receives the funding such as: “The University of X receives a support grant from Company Y, who is the sponsor of this clinical trial”.

#### **DATA PROTECTION ELEMENTS**

Ensure the consent form contains statements:

- Informing the participant that national and international data protection regulations give the participant the right to control the use of his/her medical information.
- That by signing this form the participant specifically authorizes his/her medical information to be checked, transferred and processed as follows:
  - The monitors, auditors and inspectors may review the participant/s medical information by direct access to the participant’s medical records.
  - That the study data, including the participant’s anonymous medical information, may be processed, which means it will be collected, entered into computer databases, verified, analyzed, printed and reported as necessary for legitimate scientific purposes, including use in future medical or pharmaceutical research.
  - That the study data may be transferred to other countries for processing, including countries not covered by the European Privacy Directive.
  - That if the participant should withdraw from the study, study data collected prior to withdrawal may still be processed along with other data collected as part of the clinical study.
  - That the participant may access his/her medical information as allowed by national law and that if the treatment the participant received in this study needs to remain unknown (=blinded) until the study data is analyzed, the participant may access this information only after the data has been analyzed.

#### **HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) ELEMENTS**

Ensure the document contains:

- A description of the information (that will be recorded or generated) to be used or disclosed
- The identification of the persons or class or persons authorized to make the use or disclosure of the protected health information

- The identification of the persons or class or persons to whom the covered entity is authorized to make the use or disclosure
- A description of each purpose of the use and disclosure
- An expiration date or event (e.g., 01/01/25, “15 years after the end of the study”). “Never” or “no expiration date” is acceptable in all states except California
- Any restrictions or conditions applying to the authorization (e.g., states that participant’s access to health information may be revoked during his/her participation in the study)
- A statement that indicates the participant has the right to revoke his/her authorization for the use of his/her personal health data and that it must be submitted in writing
- A statement that indicates the participant has the right to refuse to sign the authorization which will result in the participant being ineligible to participate in the study
- A statement that there is a potential for information disclosed under the authorization to be re-disclosed and that this may not be protected under the same HIPAA regulations
- Instruction to the person signing the authorization of the right to receive a copy of the signed authorization
- The signature and date of the participant or authorized representative
- A space to include a description of the legally authorized representative’s authority to act for the participant

**CALIFORNIA CONFIDENTIALITY OF MEDICAL INFORMATION ACT ELEMENTS**

If the investigator site is in California, ensure the consent/authorization form(s) includes HIPAA elements and includes the following:

- All HIPAA elements in 14-point type or larger
- Authorization that is separate from any other language present on the same page
- Authorization executed by a signature which serves no other purpose than to execute the authorization (separate signature block from the informed consent signature)
- A specific date after which the health care provider is no longer authorized to disclose the medical information (e.g., 01/01/25, “50 years after the end of the study”). “Never” or “no expiration date” is not acceptable