

# Kelsey-Seybold Clinic

KELSEY-SEYBOLD CLINIC  
INSTITUTIONAL REVIEW BOARD  
CONSENT FORM CHECKLIST

<u>YES</u>	<u>NO</u>	
_____	_____	1. Is the consent form written in <u>lay</u> (understandable) <u>language</u> ?
_____	_____	2. Is it <u>free of any language</u> through which the subject is made to waive or appear to waive any legal rights, including any release of the investigator, the sponsor, the institution or its agents from liability for negligence?
_____	_____	3. If blood is to be withdrawn, is the <u>standard blood withdrawal information</u> included? e.g., amount of blood to be withdrawn (in milliliters and ounces); number of times blood is to be withdrawn; period of time covered; potential hazards, including a statement indicating that there might be "a bruise at the site of the vein puncture, inflammation of the vein and infection"; and information that "care will be taken to avoid these complications."
_____	_____	4. If <u>pregnant women</u> are to be included as subjects, provision made for using the required <u>Auditor Witness</u> to the consent procedure? Is there a statement describing accepted methods of contraceptives (i.e. oral contraceptive with a barrier method, spermicide and barrier method, or IUD.)
_____	_____	5. If <u>children</u> (over age 7) are to be included as subjects, is provision made for securing the <u>assent</u> of the child and <u>consent</u> of the parent(s) or guardian(s)?
_____	_____	6. If <u>investigational drugs or devices</u> are to be used, or if approved drugs or devices are to be used in a manner for which they have not been approved, are such drugs or devices identified as " <u>experimental</u> "?
_____	_____	7. Does the consent form include each of the <u>basic elements of informed consent</u> as follows?
_____	_____	a. A statement that the study involves <u>research</u> , an explanation of the <u>purposes</u> of the research, and the <u>expected duration</u> of the subject's participation.

- | <u>YES</u> | <u>NO</u> |  |
|------------|-----------|--|
| -----      | -----     | b. A <u>description of the procedures</u> to be followed and <u>identification of any procedures which are experimental</u> .  |
| -----      | -----     | c. A description of any reasonable <u>foreseeable risks or discomforts</u> .   |
| -----      | -----     | d. A description of any <u>benefits</u> to the patient or others.  |
| -----      | -----     | e. A disclosure of appropriate <u>alternative procedures</u> which might be advantageous to the subject.   |
| -----      | -----     | f. A statement describing the extent to which <u>confidentiality</u> of records identifying the subject will be maintained.  |
| -----      | -----     | g. In the case of research involving <u>FDA regulated products</u> , information that the FDA and the study sponsor may inspect records identifying subjects.  |
| -----      | -----     | h. For research involving <u>more than minimal risk</u> , the appropriate " <u>compensation statement</u> " depending upon where the research is to be conducted.  |
| -----      | -----     | i. An explanation of whom to contact for <u>answers to pertinent questions involving the research and research subject's rights, and whom to contact in the event of research-related illness or injury</u> to the subject as follows:<br><br>"Questions about your rights as a research study participant can be directed to Sandra Johnson, Institutional Review Board Coordinator, Kelsey-Seybold Clinic, at 713-442-1214." The appropriate name and phone number of a Kelsey-Seybold Clinic, physician to contact in case of a research-related illness of injury to the research subject must also be included on the consent form. |
| -----      | -----     | j. A statement that <u>participation is voluntary</u> , that refusal to participate will involve <u>no penalty or loss of benefits</u> and that the subject may <u>discontinue participation at any time without penalty of loss of benefits</u> .   |

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- | <u>YES</u> | <u>NO</u> |   |
|------------|-----------|---|
| _____      | _____     | k. The statement for Kelsey-Seybold Clinic's disclaimer statement is as follows:<br><br>"In the event of physical illness or injury resulting from this research, Kelsey-Seybold Clinic and any of its agents including but not limited to investigators, shareholders, physicians and employees are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment, and professional services will be available to research subjects, just as they are to the community generally." |
| _____      | _____     | l. Is there a line for the subject to initial should at the bottom of each page of the informed consent. Are there page numbers at the bottom of each page of the informed consent.   |
| _____      | _____     | m. Are the informed consents titled Kelsey-Seybold Clinic Informed Consent.*  |

If there is a "NO" response to any of the above questions, the consent form must be revised accordingly.

\* Indicates statements specifically required by Kelsey-Seybold Clinic.