

Bronson Methodist Hospital Institutional Review Board

Checklist for Creating an Informed Consent

NOTE: A Health Insurance Portability and Accountability Act (HIPAA) Authorization should either be incorporated into the consent document or may be a separate document. The HIPAA authorization will require Institutional Review Board (IRB) review and should be submitted with the application package.

1. Format/Style:

- ___ Informed Consent should be written using laymen's terms.
- ___ Informed Consent should be written in second person (i.e. you, your; avoid I, my, etc.).
- ___ Font size should be no less than 12 point.
- ___ Leave a bottom margin of at least 1.5 inches on the signature page for the IRB approval stamp.
- ___ Header should contain study title, PI's name, and BMH #___; footer should contain date/version, page/total pages, and a line for participant initials.
- ___ **Readability:** Flesch-Kincaid Grade Level should be \leq 8th grade. The readability grade level for this Informed Consent is ___.

2. Required elements for informed consent:

- ___ Introductory paragraph includes a statement that the study involves **research**.
- ___ Explanation of the purpose of the research.
- ___ The expected duration of the subjects' participation in the trial.
- ___ Conditions for participation (i.e. inclusion/exclusion criteria).
- ___ Description of procedures to be followed, including all invasive procedures.
- ___ Identify any experimental procedures.
- ___ Description of any reasonably foreseeable **risksⁱ, discomforts, or inconveniences** to the subject.
- ___ Identify any reasonable benefits to the subject or society that may be expected from the research.
- ___ When there are no expected benefits, the subject should be informed.
- ___ The anticipated prorated payment, if any, to the subject for participating in the research.
- ___ A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject.
- ___ A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
- ___ The following statement should be included in all consents except anonymous surveys:
*"The investigators and (**institution where study will be conducted**) will keep confidential all information related to this research study to the extent permitted by laws and regulations. The U. S. Food and Drug Administration, health authorities, the Bronson Methodist Hospital Institutional Review Boardⁱⁱ, or legal actions may require disclosure or be granted direct access to the subject's medical records pertaining to the study for verification of clinical investigational procedures and/or data. This release of information would be accomplished without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations. By signing a written informed consent document, the subject or the subject's legally acceptable representative is authorizing such access. If the results of this study are published, or presented at medical meetings, you will not be identified in any way."*
- ___ For research involving more than minimal riskⁱ, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained (see Bronson Informed Consent Template).

____ The investigator's name and telephone number should be included as well as the IRB contact information as follows:

"You may contact (investigator name) at (phone number [also include a 24-hour contact number if available]) to answer questions related to the study, including withdrawing from the study. The Bronson Methodist Hospital Institutional Review Board (IRB) has approved this consent form and study. The IRB is a group of scientific and non-scientific people who review and approve or disapprove research involving people by following the Food and Drug Administration (FDA) rules. This group is also required by the FDA to do periodic review of ongoing research studies. Questions about your rights as a volunteer may be addressed to: James W. Carter, MD, Chairman, Bronson Methodist Hospital Institutional Review Board, 601 John Street (Box 80), Kalamazoo, MI 49007 or you may call 269-341-7898 between the hours of 8:30 a.m. and 5:00 p.m."

____ A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

3. One or more of the following elements shall also be contained in the informed consent, as applicable:

____ Statement that a particular treatment/procedure may involve risks to the subject or to an embryo, fetus, or nursing infant, or if subject becomes pregnant that are currently unforeseeable.

____ Disclosure of financial interests to research subjects (refer to document "Informed Consent Disclosure Model Language").

____ The foreseeable circumstances and/or reasons under which the investigator may terminate the subject's participation regardless of the consent.

____ Subject's responsibilities.

____ Any additional costs to the subject that may result from participation in the research.

____ Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

____ Statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue, will be provided to the subject.

____ The approximate number of subjects involved in the trial (preferably based on power analysis computations).

____ Study treatment(s) and the probability for random assignment to placebo or to each treatment.

Note: An Assent Form is required for subjects less than 18 years old. Please ask for these guidelines if needed.

Reference: DHHS 45CFR46; FDA 21CFR 50, 21CFR56; ICH E6

ⁱ **Minimal Risk:** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

Risk: The probability of harm or injury (risks include, but are not limited to: physical, psychological, social, economic, community, legal, financial, employability, insurability, academic standing, or other.) occurring because of participation in a research study. Both the probably and magnitude of possible harm may vary from minimal to significant.

ⁱⁱ **An Institutional Review Board (IRB)** is a committee made up of physicians, nurses, scientists, non-scientists, and community members whose primary responsibility is to protect the rights and welfare of human research participants.