Consent \ Assent Checklist

Federally Required Elements of Informed Consent

DHHS 45 CFR 46 & FDA 21 CFR 50

Yes	No	N/A	General Informed Consent Requirements:
			(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
			(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
			(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
			✶ (4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
			✶ (5) (i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
			✶ (ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
			(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Yes	No	N/A	Basic elements of informed consent - unless the IRB has approved a waiver or alteration of informed consent, the following information must be provided to each subject or the legally authorized representative:
			(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
			(2) A description of any reasonably foreseeable risks or discomforts to the subject;
			(3) A description of any benefits to the subject/others that may reasonably be expected from the research;
			(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
			(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
			(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
			(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

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Yes	No	N/A	**Basic elements of informed consent - unless the IRB has approved a waiver or alteration of informed consent, the following information must be provided to each subject or the legally authorized representative:**
			(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
			✶(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; **or** (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Yes	No	N/A	**Additional elements of informed consent - the following elements of information, when appropriate, must also be provided to each subject or the legally authorized representative** (if applicable)**:**
			(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
			(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
			(3) Any additional costs to the subject that may result from participation in the research;
			(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
			(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
			(6) The approximate number of subjects involved in the study;
			✶ (7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
			✶ (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
			✶ (9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Yes	No	N/A	**Additional FDA Related Statements** (include in addition to the above, if applicable):
			Purpose should indicate if study will test or collect data on an FDA regulated product. (e.g., test safety and effectiveness). Proof of concept or early feasibility research may test “how something works” instead of “how well it works”. Indicate if results will be shared with FDA;
			Description includes reference to FDA approval status or specific use in study (i.e., FDA has approved ___ for some uses but not for your specific disease). Listing approval status is more meaningful than ambiguous terms like “investigational”;

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Yes	No	N/A	**Additional FDA Related Statements** (include in addition to the above, if applicable):
			Sections discussing confidentiality should indicate that FDA may look at or copy pertinent portions of records;
			Applicable FDA regulated clinical trials statement regarding registration and results posting on Clinicaltrials.gov- Exact statement from 21 CFR 50.25(c); and 3/7/2012
			For FDA studies, (if not covered in HIPAA Authorization section of consent), indicate that if subject withdraws from study early, the data collected until that point remains in the study database and may not be removed.
			Other Statements Required by UK IRB (if applicable)
			Information concerning payment including but not limited to amount and schedule of payment.

Yes	No	N/A	**Assent** (if applicable)
			For studies involving children capable of assent, propose a process that takes into account, oral and written communication; illustrates respect for the child; conveys voluntary nature of decision; and includes information the child requires, in a manner he/she can understand, in order to make a decision about participating in the research.
			For children at an age, maturity, and degree of literacy, develop a simplified Assent Form using format and language appropriate for the study population.
			If young children are involved who are yet unable to read, develop an assent script, which provides young children with information in a format that facilitates a voluntary decision whether or not to assent. Documentation should take a form that is appropriate for the purpose of recording that assent took place.

Yes	No	N/A	**Sample Statements Required by Sponsors**
			For studies with a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH), FDA or other agency – include language informing research participants of the protections and the limits to protections provided by the CoC. 12/13/2016
			Studies subject to the NIH Genomic Data Sharing (GDS) Policy (i.e., NIH-funded projects that generate large-scale genomic data) NIH expects investigators to obtain consent to share participants' genomic and phenotypic data broadly through databases. Include language to specify if the data will be shared via unrestricted- or controlled-access databases, or both. See the UK Sample Repository/Registry/Bank Consent
			NIH Funded Clinical Trials clinical trials statement regarding registration and results posting on Clinicaltrials.gov 1/18/2017

✶ = Not enforceable for protocols approved prior to 1/21/19 (Pre-2019)

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