

Comparison of Various Informed Consent Regulations

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DEFINITIONS 102.	DEFINITIONS 50.3	1. Glossary	
<p>()</p> <p>Informed Consent</p>	<p>()</p> <p>Informed Consent</p>	<p>1.28</p> <p>INFORMED CONSENT</p> <p>A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.</p>	<p>24173</p> <p>"Informed consent" means the authorization given pursuant to Section 24175 to have a medical experiment performed after each of the following conditions have been satisfied:</p> <p>(Paraphrased)</p> <p>(a) Experimental Subjects Bill of Rights given</p> <p>(b) wring consent form signed and dated</p> <p>(c) subject is informed...</p>
<p>(c).</p> <p>Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.</p>	<p>m)</p> <p>Legally Authorized Representative" means an individual or juridical or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures(s) involved in the research.</p>	<p>1.37</p> <p>Legally Acceptable Representative</p> <p>An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.</p>	<p>24175</p> <p>(b) If a person is under a conservatorship....</p> <p>(c) If an adult person is gravely disabled,</p> <p>(d) If an adult person is developmentally disabled</p> <p>Informed consent given by a person other than the human subject ... shall only be for medical experiments related to maintaining or improving the health of the human subject or related to obtaining information about a pathological condition of the human subject.</p>
	<p>n) Family member means any one of the following legally competent persons: Spouse; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.</p>	<p>1.26 Impartial Witness A person who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.</p>	
<p>GENERAL REQUIREMENTS 46.116</p> <p>Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.</p>	<p>50.20 General Requirements for Informed Consent</p> <p>Except as provided in § 50.23, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.</p>	<p>4.8 INFORMED CONSENT OF TRIAL SUBJECTS</p> <p>4.8.1 In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s). and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki....</p>	<p>COMPILED BY ERICA HEATH DECEMBER 1999</p>

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<p>An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.</p>	<p>An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.</p>	<p>4.8.3 Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.</p> <p>4.8.7 Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial.</p> <p>All questions about the trial should be answered to satisfaction of the subject or the subject's legally acceptable representative.</p>	<p>24173 Def of Informed consent</p> <p>(e) Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative as specified by Section 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.</p>
<p>The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.</p>	<p>The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.</p>	<p>4.8.6 The language used in the oral and written information about the trial, including the written informed consent form should be as nontechnical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.</p>	
<p>No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.</p>	<p>No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.</p>	<p>None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence</p>	

OBTAINING CONSENT

	<p>312.60 Responsibilities of Investigators</p> <p>... An investigator shall, in accordance with the provisions of part 50 of this chapter, obtain the informed consent of each subject to whom the drug is administered, except as provided in §§ 50.23 or 50.24 of this chapter...</p> <p>812.100</p> <p>... An investigator also is responsible for ensuring that informed consent is obtained in accordance with Part 50 of this chapter.</p>	<p>4.8.5 The investigator or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information given approval/favorable opinion by the IRB/IEC.</p>	
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ELEMENTS OF CONSENT

<p>45 CFR 46.116</p> <p>A) Basic required elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:</p>	<p>21 CFR 50.25</p> <p>(a) Basic required elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:</p>	<p>4.8.10</p> <p>Both the informed consent discussion and the written informed consent form and any other written information to be provided subjects should include explanations of the following:</p>	<p>24173(c)(1)</p> <p>is informed ... of the following facts of the proposed medical experiment which might influence the decision to undergo the experiment, including, but not limited to:</p>
<p>1. A statement that the study involves research,</p>	<p>1. A statement that the study involves research,</p>	<p>a That the trial involves research,</p>	

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an explanation of the purpose of the research	an explanation of the purpose of the research	b. The purpose of the trial,	
the expected duration of the subject's participation	the expected duration of the subject's participation,	s. The expected duration of the subject's participation in the trial.	
a description of the procedures to be followed,	a description of the procedures to be followed,	d. The trial procedures to be followed including all invasive procedures	(1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purpose of such procedures, drugs or devices.
and identification of any procedures which are experimental,	and identification of any procedures which are experimental,	f. Those aspects of the trial that are experimental	
2. A description of any reasonably foreseeable risks or discomforts to the subject,	2. A description of any reasonably foreseeable risks or discomforts to the subject,	g. The reasonably foreseeable risks or inconveniences to the subject and...	(2) A description of any attendant discomfort or risk to the subject reasonably to be expected.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.	3. A description of any benefits to the subject or to others which may reasonably be expected from the research.	h. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.	(3) An explanation of any benefits to the subject reasonably to be expected, if applicable.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subjects.	4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subjects.	i. The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.	(4) A disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained ,	5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records,	n. That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of the clinical trial procedures and/or data without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations, and that by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access. o. That records identifying the subject 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 subject's identity will remain confidential.	
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.	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.	j. The compensation and/of treatment available to the subject in the event of a trial-related injury.	

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<p>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.</p>	<p>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.</p>	<p>q. The person(s) to contact for further information regarding the trial and the rights of trial subjects,</p> <p>and whom to contact in the event of a trial-related injury.</p>	<p>(6) An offer to answer any inquiries concerning the experiment or the procedures involved.</p> <p>(8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.</p> <p>(9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.</p> <p>(10) The name, address and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.</p>
<p>8. A statement that participation is voluntary,</p> <p>that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and</p> <p>that the subjects may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.</p>	<p>8. A statement that participation is voluntary,</p> <p>that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and</p> <p>that the subjects may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.</p>	<p>m. That the subject's participation in the trial is voluntary and</p> <p>that the subject may refuse to participate or withdraw from the trial,</p> <p>at</p> <p>any time, without penalty or loss of benefits to which the subject is otherwise entitled.</p>	<p>(7) An instruction to the subject that he or she is free to withdraw his prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.</p>
		<p>c. The trial treatment(s) and the probability for random assignment to each treatment.</p>	
<p>ADDITIONAL OPTIONAL ELEMENTS OF CONSENT</p>	<p>ADDITIONAL OPTIONAL ELEMENTS OF CONSENT</p>	<p>e. The subjects responsibilities</p>	<p>(5) An estimate of the expected recovery time of the subject after the experiment.</p>
<p>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) which are currently unforeseeable.</p>	<p>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) which are currently unforeseeable.</p>	<p>k. The anticipated prorated payment, if any, to the subject for participating in the trial</p>	
<p>2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.</p>	<p>2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.</p>	<p>g. (risks) and, when applicable, to an embryo, fetus, or nursing infant.</p>	
<p>3. Any additional costs to the subject that may result from participation in this study,</p>	<p>3. Any additional costs to the subject that may result from participation in this study,</p>	<p>r. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.</p>	
<p>4 The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.</p>	<p>4 The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.</p>	<p>l. The anticipated expenses, if any to the subject for participating in the trial.</p>	

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5. A statement that significant new findings developed during the course of the research which may relate to the subjects willingness to continue participation will be provided to the subject,	5. A statement that significant new findings developed during the course of the research which may relate to the subjects willingness to continue participation will be provided to the subject,	p. That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial	
6. The approximate number of subjects involved in the study	6. The approximate number of subjects involved in the study.	t. The approximate number of subjects involved in the trial.	
	56.109(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §50.25. The IRB may require that information, in addition to that specifically mentioned in §50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of the subjects.		24173(c)(1) If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of such experiments shall be informed of such fact, however, they need not be informed as to whether they will actually be administered or dispensed a placebo.
DOCUMENTATION OF INFORMED CONSENT 46.109	DOCUMENTATION OF INFORMED CONSENT 50.27		
(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information in addition to that specifically mentioned in §46.116 be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects. (c) An IRB shall require documentation of informed consent or may waive documentation in accordance with 46.117.	(a) Except as provided in § 56.109 (C) informed consent shall be documented by the use of a written consent form approved by the IRB and <i>signed and dated by</i> the subject or the subject's legally authorized representative.	4.8.8 Prior to a subject's participation in the trial, the written informed consent form should be <i>signed and personally dated</i> by the subject or by the subjects legally acceptable representative, and by the person who conducted the informed consent discussion. 4.8.11 Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed dated consent form updates and a copy of any amendments to the written information provided to subjects.	24173 Def. of Informed Consent (b) The written consent form is signed and dated by the subject or the subject's conservator or guardian or other representative, as specified in section 24175.
46.117(a) A copy shall be given to the person signing the form.	50.27(a) A copy shall be given to the person signing the form.		
46.117 (a) Except as provided in paragraph (c) of this section informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative (b) Except as provided in paragraph (c) of this section the consent form may be either of the following:	(b) Except as provided in 56.109(c) the consent form may be either of the following	4.8.13 Except as described in 4.8.14, a nontherapeutic trial (i.e., a trial in which there is no anticipated direct clinical benefit to the subject) should be conducted in subjects who personally give consent and who sign and date the written informed consent form.	

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<p>1 A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.</p>	<p>1 A written consent document that embodies the elements of informed consent required by § 50.25. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.</p>		
<p>2 A "short form" written consent document stating that the elements of informed consent required by 46.1160 have been presented orally to the subject or the subject's legally authorized representative.</p>	<p>2 A "short form" written consent document stating that the elements of informed consent required by § 50.25 have been presented orally to the subject or the subject's legally authorized representative.</p>		
<p>When this method is used, there shall be a witness to the total presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.</p>	<p>When this method is used, there shall be a witness to the total presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.</p>		
WAIVERS AND DEVIATIONS			
<p>Exception from general requirements 46.116</p> <p>(C) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:</p>	<p>Exception from general requirements 50.23</p> <p>(a) The <i>obtaining of</i> informed consent shall be deemed feasible unless, before use of the test article (except as provided in paragraph (b) of this section), both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:</p>	<p>4.8.12 When a clinical trial (therapeutic or nontherapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject's legally acceptable representative (e.g., minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should assent, sign and personally date the written informed consent.</p>	<p>24178 Except for ... the Experimental Subjects Bill of Rights and the penalties, this chapter shall not apply to any person who is conducting a medical experiment as an investigator within an institution which holds an assurance with the Department of Health, Education and Welfare pursuant to Part 46 of Title 45 of the Code of Federal Regulations and who obtains informed consent in the method and manner required by such regulation</p>

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<p>1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:</p> <ul style="list-style-type: none"> i) Public benefit of service programs; ii) procedures for obtaining benefits or services under those programs; iii) possible changes in or alternatives to those programs or procedures, or iv) possible changes in methods or levels of payment for benefits or services under these programs; and <p>2) The research could not practicably be carried out without the waiver or alternation.</p>	<ul style="list-style-type: none"> 1. The human subject is confronted by a life-threatening situation necessitating the use of the test article. 2. Informed consent cannot be obtained from the subject because of an inability to communicate with or obtain legally effective consent from the subject. 3. Time is not sufficient to obtain consent from the subject's legal representative 4. There is no available alternative method of approved or generally recognized therapy that provides and equal or greater likelihood of saving the life of the subject. 	<p>4.8.14 Nontherapeutic trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled:</p> <ul style="list-style-type: none"> a) The objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally. b) The foreseeable risks to the subjects are low c) The negative impact on the subject's well-being is minimized and low. d) The trial is not prohibited by law. e) The approval/favorable opinion of the IRB/IEC is expressly sought on the inclusion of such subjects and the written approval/favorable opinion covers this aspect. <p>Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Subjects in those trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.</p>	
<p>d) An IRB may approve a consent <i>procedure</i> which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:</p> <ul style="list-style-type: none"> 1) the research involves no more than minimal risk to the subjects. 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; 3) the research could not practicably be carried out without the waiver or alternation, and 4) whenever appropriate, the subjects will be provided with additional pertinent information after participation. 			
<p>46.117 (c)</p> <p>An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:</p> <ul style="list-style-type: none"> 1) that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or 2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. 	<p>56.109(C)</p> <p>An IRB shall require documentation of informed consent in accordance with §50.27, of this chapter except as follows:</p> <ul style="list-style-type: none"> 1) The IRB may, for some or all subjects, waive the requirement that the subject, or the subject's legally authorized representative, sign a written consent form if it finds that <ul style="list-style-type: none"> the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context, or <p>In cases where the documentation requirement is waived, under paragraph (c)(1) of this section, the IRB may require the investigator to provide subjects with a written statement regarding the research.</p>		

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VULNERABLE SUBJECTS			
45 CFR 46 Subparts B, C, and D.	No special regulations		
EMERGENCY RESEARCH			
	50.24	4.18.15	
	2) The IRB may, for some or all subjects, find that the requirements in §50.24 of this chapter for an exception from informed consent for emergency research are met.	... enrollment should require measures described in the protocol and/or elsewhere....	