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# Comparison of FDA Regulations (Current and Proposed) & Common Rule

The FDA Regulations cited in this table are primarily from 21 CFR 50 and 56 as these regulations refer to human subject protection and institutional review boards (IRBs). The proposed FDA changes cited in this table are from FDA proposed rules Protection of Human Subjects and Institutional Review Boards and Institutional Review Boards; Cooperative Research.

The proposals, if finalized would harmonize certain sections of FDA's regulations on human subject protection and institutional review boards (IRBs), to the extent practicable and consistent with other statutory provisions, with the revised Federal Policy for the Protection of Human Subjects (the revised Common Rule), in accordance with the 21st Century Cures Act (Cures Act). This table does not attempt to comprehensively address all FDA requirements nor to capture every minor change or nuance in the proposed amendments to the regulations.

Regulatory text has been summarized or paraphrased in some instances for the purposes of this table, refer to the cited regulations for the exact text.

 

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| REGULATIONS ON HUMAN SUBJECT RESEARCH | 21 CFR 50 (Protection of Human Subjects): Subpart A (scope & definitions), Subpart B (informed consent), Subpart D (children). **Note:** No subparts for prisoners or pregnant women/fetus/neonates.<br><br>21 CFR 56 (Institutional Review Boards)<br><br>21 CFR 54 (Financial Disclosure by Clinical Investigators)<br><br>21 CFR 11 (Electronic Records, Signatures)<br><br>21 CFR 312 (Investigational New Drug Application)<br><br>21 CFR 809 (In Vitro Diagnostic Products for Human Use)<br><br>21 CFR 812 (Investigational Device Exemption)<br><br>21 CFR 814: Subpart H (Humanitarian Use Devices)<br><br>**Note:** This is a listing of the most relevant FDA regulations, not a complete listing of all FDA regulations. | Note, there are proposed revisions to 50, 56 and 812. | Subpart A "Basic HHS Policy for Protection of Human Research Subjects" (the "Common Rule")<br><br>Subparts B, C, and D. Regulations provide additional protections for pregnant women/fetus/neonates, prisoners, and children<br><br>**Note:** Federal depts and agencies that adopt the Common Rule may choose not to adopt Subparts B, C, and/or D or may develop dept or agency specific subparts. |
| AUTHORITY | **[21 CFR 50]** 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 352, 353, 355, 360, 360c-360f, 360h-360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262.<br><br>**[21 CFR 56]** 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 351, 352, 353, 355, 360, 360c-360f, 360h, 360i, 360j, 360hh-360ss, 371, 379e, 381; 42 U.S.C. 216, 241, 262. | **MODIFIED 21 CFR 50** to read:<br><br>21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 352, 353, 355, 360, 360c–360f, 360h–360j, 360hh–360pp, 360rr–360ss, 371, 379e, 381; 42 U.S.C. 216, 241, 262. | N/A |

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| SCOPE | **[21 CFR 50.1]** (a) This part applies to all clinical investigations regulated by the FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act (the Act), as well as clinical investigations that support applications for research or marketing permits for products regulated by the FDA, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Additional specific obligations and commitments of, and standards of conduct for, persons who sponsor or monitor clinical investigations involving particular test articles may also be found in other parts (e.g., parts 312 and 812). Compliance with these parts is intended to protect the rights and safety of subjects involved in investigations filed with the FDA pursuant to sections 403, 406, 409, 412, 413, 502, 503, 505, 510, 513-516, 518-520, 721, and 801 of the Act and sections 351 and 354-360F of the PHS Act.<br><br>(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.<br><br>**[21 CFR 56.101]** (a) This part contains the general standards for the composition, operation, and responsibility of an IRB that reviews clinical investigations regulated by the FDA under sections 505(i) and 520(g) of the Act, as well as clinical investigations that support applications for research | **MODIFIED 50.1(a)** to read:<br><br>(a) …Compliance with these parts is intended to protect the rights and safety of subjects involved in investigations ~~filed with the FDA pursuant to sections 403, 406, 409, 412, 413, 502, 503, 505, 510, 513-516, 518-520, 721, and 801 of the Act and sections 351 and 354-360F of the PHS Act~~.<br><br>**REMOVED from 56.103(a)** reference to Part "813" of this chapter.<br><br>**MODIFIED 56.103(c)** to state:<br><br>(c) Compliance with these regulations will in no way render inapplicable pertinent Federal, State or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may be applicable and that provide additional protections for human subjects. | **[46.101]** (a) Except as detailed in 46.104, this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States. Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy.<br><br>(b) [Reserved]<br><br>(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy and this judgment shall be exercised consistent with the ethical principles of the Belmont Report.<br><br>(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the Federal department or agency but not otherwise covered by this policy comply with some or all of the requirements of this policy. |

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| | or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with this part is intended to protect the rights and welfare of human subjects involved in such investigations.<br><br>(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.<br><br>**[21 CFR 56.103]** (a) Except as provided in 56.104 and 56.105, any clinical investigation which must meet the requirements for prior submission (as required in parts 312, 812, and 813) to the FDA shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of this part.<br><br>(b) Except as provided in 56.104 and 56.105, the FDA may decide not to consider in support of an application for a research or marketing permit any data or information that has been derived from a clinical investigation that has not been approved by, and that was not subject to initial and continuing review by, an IRB meeting the requirements of this part. The determination that a clinical investigation may not be considered in support of an application | | (e) Compliance with this policy requires compliance with pertinent federal laws or regulations that provide additional protections for human subjects.<br><br>(f) This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.<br><br>(g) This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research.<br><br>(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the Federal Register or will be otherwise published as provided in department or agency procedures. |

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| | for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulations to submit the results of the investigation to the Food and Drug Administration.<br><br>(c) Compliance with these regulations will in no way render inapplicable pertinent Federal, State, or local laws or regulations.<br><br>**[21 CFR 814.124] Humanitarian Use Devices**: The HDE holder is responsible for ensuring that a HUD approved under this subpart is administered only in facilities having oversight by an Institutional Review Board (IRB) constituted and acting pursuant to part 56 of this chapter, including continuing review of use of the device.<br><br>**[56.103] Note:** There are additional statements of scope throughout each section of the FDA regulations. | | (i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities… **Note:** See section WAIVER OF IRB REVIEW OR OTHER REQUIREMENTS in this document for more on 46.101(i).<br><br>(j) Federal guidance on the requirements of this policy shall be issued only after consultation, for the purpose of harmonization (to the extent appropriate), with other Federal departments and agencies that have adopted this policy, unless such consultation is not feasible.<br><br>(k) [Reserved]<br><br>(l) Compliance dates and transition provisions Note**:** An equivalent section is not included in the current FDA proposals. See 45 CFR 46.101(l) for complete text.<br><br>(m) Severability: Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances. |

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| ASSURANCES, CERTIFICATION, AND IRB REGISTRATION | **Note:** FDA **does not** require a federal assurance nor certification of IRB approval from institutions. Investigators, and sponsors, are responsible for ensuring that non-exempt clinical investigations have IRB approval under parts 312 and 812. HDE holders are responsible for ensuring IRB approval under part 814.<br><br>**Summary of 56.106: Registration.** FDA does require prospective registration of each IRB in the US that reviews clinical investigations regulated by the FDA. Registration is through the OHRP electronic IRB registration site. The registration must include:<br><br>(1) The institution name and address and the name and contact information of the senior official who is responsible for overseeing IRB activities<br>(2) The IRBs name and address, the IRB Chair's name and contact information, and the name and contact information of the IRB contact person<br>(3) The approximate number of active protocols involving FDA-regulated products<br>(4) A description of the types of FDA-regulated products that the IRB reviews<br><br>The registration must be renewed every 3 years. The registration must be revised within set time frames if:<br><br>(1) The IRB Chair or contact person, or their information, changes | **ADDED** new paragraph **56.118(a)(8)** which is consistent with the revised Common Rule's requirements at 45 CFR 46.103(e) and 45 CFR 46.115(a)(9).<br><br>**56.115(a)(8)** For research that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, documentation specifying the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this part (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol). | **Summary of 46.103: Assuring compliance with this policy—research conducted or supported by any Federal department or agency.** This section requires that each institution engaged in research covered by the Common Rule provide written assurance that it will comply with the requirements of the Common Rule and states the minimum requirements for an assurance. (See 46.103(a)-(c) for complete text).<br><br>**[46.103(d)]** requires certification of IRB approval for non-exempt research unless the requirement has been waived. (See 46.103(d) for complete text).<br><br>**[46.103(e)]** For nonexempt research involving human subjects covered by this policy (or exempt research for which limited IRB review takes place pursuant to § 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8)) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol). Note**:** Limited IRB review and broad consent are not included in the current FDA proposals. |

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| | (2) The IRB will begin reviewing additional categories of FDA-regulated products (e.g., drug, device)<br>(3) The IRB will discontinue reviewing FDA-regulated research<br>(4) The IRB disbands<br><br>Note: The underlined text is not included in the Common Rule. | | **Subpart E** requires that each IRB that is designated by an institution under an FWA and that reviews research involving human subjects conducted or supported by the DHHS must be registered with DHHS. Registration is through the OHRP electronic IRB registration site. The registration must include:<br>(1) The name and address of the institution or organization operating the IRB and the contact information for the senior official who is responsible for overseeing IRB activities<br>(2) The name and contact information of the contact person providing the registration information<br>(3) The IRB's name, if any, and address and contact information<br>(4) The IRB Chair's name and contact information<br>(5) The approximate numbers of: (i) all active protocols; and (ii) active protocols conducted or supported by DHHS<br>(6) The approximate number of FTE's devoted to the IRB's administrative activities<br><br>The registration must be renewed every 3 years. The registration must be updated within set time frames if:<br>(1) The IRB Chair or contact person, or their information, changes<br>(2) The IRB disbands |

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| WAIVER OF IRB REVIEW OR OTHER REQUIREMENTS | **[56.105]** On the application of a sponsor or sponsor-investigator, the Food and Drug Administration may waive any of the requirements contained in these regulations, including the requirements for IRB review, for specific research activities or for classes of research activities, otherwise covered by these regulations. | N/A | **[46.101] (i)** Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy, provided the alternative procedures to be followed are consistent with the principles of the Belmont Report. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, or to the equivalent office within the appropriate Federal department or agency, and shall also publish them in the Federal Register or in such other manner as provided in department or agency procedures. The waiver notice must include a statement that identifies the conditions under which the waiver will be applied and a justification as to why the waiver is appropriate for the research, including how the decision is consistent with the principles of the Belmont Report. |
| IRB MEMBERSHIP REQUIREMENTS | **[56.107]** (a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its | **MODIFIED 56.107(a)** to read:<br><br>(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its ~~the~~ members, including consideration of race, gender, cultural backgrounds, | **[46.107]** (a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel |

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| | advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. * * * The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.<br><br>(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession. | and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. ~~In addition to possessing the professional competence necessary to review the specific research activities, t~~ The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. * * * The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a ~~vulnerable~~ category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, ~~pregnant women, or handicapped~~ or economically or educationally disadvantaged ~~mentally disabled~~ persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with ~~those~~ these categories of subjects.<br><br>**REMOVED 56.107 paragraph (b)** because the requirement for IRB membership diversity would be included in 56.107(a); redesignate remaining sections which results in references (b)-(e) matching with the revised Common Rule. | in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects. |
| IRB FUNCTIONS AND OPERATIONS | **[56.108]** In order to fulfill the requirements of these regulations, each IRB shall: | **MODIFIED 56.108**: The IRB roster detail requirements formerly in old section 56.115(a)(5) have been | **[46.108]** (a) In order to fulfill the requirements of this policy each IRB shall: |

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| | (a) Follow written procedures:<br>(1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;<br>(2) for determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;<br>(3) for ensuring prompt reporting to the IRB of changes in research activity; and<br>(4) for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.<br>(b) Follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the FDA of: (1) Any unanticipated problems involving risks to human subjects or others; (2) any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or (3) any suspension or termination of IRB approval.<br>(c) Except when an expedited review procedure is used (see 56.110), review proposed research at | included at 56.108(a)(2). Editorial changes were made to harmonize the language with the revised Common Rule.<br>(a) In order to fulfill the requirements of these regulations, each IRB shall:<br>(1) Reserved;<br>(2) Prepare and maintain a current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant;<br>(3) Establish and follow written procedures for:<br>~~(1) for~~ (i) Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;<br>~~(2) for~~ (ii) Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review; | (1) Have access to meeting space and sufficient staff to support the IRB's review and recordkeeping duties; Note: This is not included in the current FDA proposals.<br>(2) Prepare and maintain a current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant;<br>(3) Establish and follow written procedures for:<br>(i) Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;<br>(ii) Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and<br>(iii) Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB |

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| | convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. | ~~(3) for~~ (iii) Ensuring prompt reporting to the IRB of proposed changes in research activity; and ~~(4)~~ for ensuring that investigators will conduct the ~~changes in approved~~ research activity in accordance with the terms of the~~, during the period for which~~ IRB approval until any proposed changes have ~~has already~~ been reviewed ~~given, may not be initiated without IRB review~~ and approved by the IRB ~~approval~~ except when ~~where~~ necessary to eliminate apparent immediate hazards to the ~~human~~ subject~~s~~.<br><br>(4) Establish and ~~(b)~~ follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of:<br><br>~~(1)~~ (i) Any unanticipated problems involving risks to ~~human~~ subjects or others~~; (2)~~ or any ~~instance of~~ serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; and ~~or~~<br><br>~~(3)~~ (ii) any suspension or termination of IRB approval.<br><br>(b)~~(c)~~ Except when an expedited review procedure is used (as described in §56.110), an IRB must ~~see §56.110),~~ review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order | approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.<br>(4) Establish and follow written procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of<br>(i) Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and<br>(ii) Any suspension or termination of IRB approval.<br><br>(b) Except when an expedited review procedure is used (as described in § 46.110), an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. |

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| | | for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. | |
| IRB REVIEW | **[56.109]** (a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.<br><br>(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 subjects.<br><br>(c) An IRB shall require documentation of informed consent in accordance with 50.27 of this chapter, except as follows:<br><br>(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 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<br>(2) The IRB may, for some or all subjects, find that the requirements in 50.24 of this chapter | **MODIFIED 56.109:** Clarifies that subjects *or LARs* must be given informed consent information in accordance with 50.25. Adds a new exception to the requirement for documentation of informed consent. Adds circumstances under which IRB continuing review can be eliminated.<br><br>**Modified** paragraph (b):<br><br>(b) An IRB shall require that information given to subjects or LARs, when appropriate, as part of informed consent is in accordance with §50.25 of this chapter. The IRB may require that information, in addition to that specifically mentioned in §50.25 of this chapter, 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.<br><br>**Added** new paragraph (c)(3) for waiver of documentation of informed consent for groups where signing forms is not the norm, which corresponds with the Common Rule 46.117(c)(1)(iii). See section WAIVER OF DOCUMENTATION OF INFORMED CONSENT in this document for details.<br><br>**Modified** paragraphs (d) and (f):<br><br>(d) In cases where the documentation requirement is waived under (c)(1) or (3), the IRB may require the | **[46.109]** (a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, *including exempt research activities under § 46.104 for which limited IRB review is a condition of exemption (under § 46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8))*. Note: The italicized text is not included in the current FDA proposals.<br><br>(b) An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) 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.<br><br>(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117.<br><br>(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for |

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| | for an exception from informed consent for emergency research are met.<br><br>(d) 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.<br><br>(e) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. For investigations involving an exception to informed consent under 50.24 of this chapter, an IRB shall promptly notify in writing the investigator and the sponsor of the research when an IRB determines that it cannot approve the research because it does not meet the criteria in the exception provided under 50.24(a) of this chapter or because of other relevant ethical concerns. The written notification shall include a statement of the reasons for the IRB's determination.<br><br>(f) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research. | investigator to provide subjects or legally authorized representative with a written statement regarding the research.<br><br>(f) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, except as described in paragraph g of this section. *(new)*<br><br>**Added** new paragraphs (g) and (h):<br><br>(g) Unless an IRB determines otherwise, continuing review of research is not required for research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:<br><br>(1) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or<br>(2) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.<br><br>(h) An IRB shall have the authority to observe or have a third party observe the consent process and the research. *(moved from (f))*<br><br>**Moved** (from (g)):<br><br>(i) An IRB shall provide in writing to the sponsor of the research involving an exception to informed consent under 50.24 of this chapter, a copy of information that has been publicly disclosed under 50.24(a)(7)(ii) | its decision and give the investigator an opportunity to respond in person or in writing.<br><br>(e) An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in § 46.109(f).<br><br>(f)<br><br>(1) Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:<br>(i) Research eligible for expedited review in accordance with § 46.110; Note: This is not included in the current FDA proposals.<br>(ii) Research reviewed by the IRB in accordance with the limited IRB review described in § 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8); Note: This is not included in the current FDA proposals.<br>(iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:<br>(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or<br>(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.<br><br>(2) [Reserved] |

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| | (g) An IRB shall provide in writing to the sponsor of research involving an exception to informed consent under 50.24 of this chapter a copy of information that has been publicly disclosed under 50.24(a)(7)(ii) and (a)(7)(iii) of this chapter. The IRB shall provide this information to the sponsor promptly so that the sponsor is aware that such disclosure has occurred. Upon receipt, the sponsor shall provide copies of the information disclosed to FDA.<br><br>(h) When some or all of the subjects in a study are children, an IRB must determine that the research study is in compliance with part 50, subpart D of this chapter, at the time of its initial review of the research. When some or all of the subjects in a study that was ongoing on April 30, 2001, are children, an IRB must conduct a review of the research to determine compliance with part 50, subpart D of this chapter, either at the time of continuing review or, at the discretion of the IRB, at an earlier date. | and (iii). The IRB shall provide this information to the sponsor promptly so that the sponsor is aware that such disclosure has occurred. Upon receipt, the sponsor shall provide copies of the information disclosed to the FDA.<br><br>**Moved** (from (h)) and **modified** to remove the last sentence referring to pediatric studies ongoing on April 30, 2001:<br><br>(j) When some or all of the subjects in the study are children, an IRB must determine that the research study is in compliance with part 50, subpart D of this chapter at the time of its initial review of the research. | (g) An IRB shall have authority to observe or have a third party observe the consent process and the research. |
| EXPEDITED REVIEW | **[56.110]** (a) The Food and Drug Administration has established, and published in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication in the Federal Register.<br><br>(b) An IRB may use the expedited review procedure to review either or both of the following: | **MODIFIED 56.110** (b) and (c) to read:<br><br>(b)<br><br>(1) An IRB may use the expedited review procedure to review either or both of the following:<br><br>(~~1~~i) Some or all of the research appearing on the list described in paragraph (a) of this section and found by the reviewer(s) to involve no more than minimal risk; | **[46.110]** (a) The Secretary of HHS has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The Secretary will evaluate the list at least every 8 years and amend it, as appropriate, after consultation with other federal departments and agencies and after publication in the Federal Register for public comment. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office. |

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| | (1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,<br>(2) minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the IRB chairperson from among the members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited review procedure set forth in § 56.108(c).<br><br>(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.<br><br>(d) The Food and Drug Administration may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects. | (~~2~~ii) Minor changes in previously approved research during the period ~~(of one year or less)~~ for which approval is authorized.<br><br>(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the IRB chairperson from among the members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited review procedure set forth in 56.108~~(c)~~**(b)**.<br><br>(c) Each IRB that ~~which~~ uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals that ~~which~~ have been approved under the procedure. | (b)<br><br>(1) An IRB may use the expedited review procedure to review the following:<br>(i) Some or all of the research appearing on the list described in paragraph (a) of this section, *unless the reviewer determines that the study involves more than minimal risk*; Note: The italicized text is not included in the current FDA proposals. FDA proposes to **maintain** the requirement that the reviewer determine that the research involves no more than minimal risk.<br>(ii) Minor changes in previously approved research during the period for which approval is authorized; or<br>(iii) Research for which limited IRB review is a condition of exemption under § 46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8). Note: This is not included in the current FDA proposals.<br>(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in |

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| | | | accordance with the nonexpedited procedure set forth in § 46.108(b).<br><br>(c) Each IRB that uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals that have been approved under the procedure.<br><br>(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure. |
| CRITERIA FOR APPROVAL | **[56.111]** (a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:<br><br>(1) Risks to subjects are minimized:<br>(i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and<br>(ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.<br>(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and | **MODIFIED 56.111** (a)(1), (3), and (5)-(7) and (b), including the description of vulnerable in criteria (a)(3) and (b).<br><br>(a)…<br><br>(1) Risks to subjects are minimized:<br>(i) By using procedures that ~~which~~ are consistent with sound research design and that ~~which~~ do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.<br><br>…<br><br>(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be | **[46.111]** (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:<br><br>(1) Risks to subjects are minimized:<br>(i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and<br>(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.<br>(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB |

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| | benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.<br>(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.<br>(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by part 50.<br>(5) Informed consent will be appropriately documented, in accordance with and to the extent required by § 50.27.<br>(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. | conducted. The IRB ~~and~~ should be particularly cognizant of special problems of research that involves a category of subjects who are ~~involving~~ vulnerable to coercion or undue influence ~~populations~~, such as children, prisoners, individuals with impaired decision-making capacity, ~~pregnant women, handicapped, or mentally disabled persons,~~ or economically or educationally disadvantaged persons.<br>…<br>(5) Informed consent will be appropriately documented or appropriately waived, in accordance with ~~and to the extent required by~~ § 50.27 of this chapter.<br>(6) (6) When ~~Where~~ appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.<br>(7) When ~~Where~~ appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.<br>(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, ~~pregnant women, handicapped, or mentally disabled persons,~~ or economically or educationally disadvantaged persons, | should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.<br>(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.<br>(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, § 46.116.<br>(5) Informed consent will be appropriately documented or appropriately waived in accordance with § 46.117.<br>(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.<br>(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.<br>(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's |

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| | (7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.<br><br>(b) When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects.<br><br>(c) In order to approve research in which some or all of the subjects are children, an IRB must determine that all research is in compliance with part 50, subpart D of this chapter. Note: This is not included in Common Rule .111 criteria. | ~~are likely to be vulnerable to coercion or undue influence~~ additional safeguards have been included in the study to protect the rights and welfare of these subjects. | privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.<br>(ii) [Reserved]<br>(8) For purposes of conducting the limited IRB review required by § 46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations: … Note: Limited IRB review and broad consent are not included in the current FDA proposals. See 45 CFR 46.111(a)(8) for complete text.<br><br>(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. |
| IRB RECORDS | **[56.115]** (a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:<br><br>(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent | **MODIFIED 56.115** (a)3, (a)5, (a)6 and (b):<br><br>(a)…<br><br>(3) Records of continuing review activities, <u>including the rationale for conducting continuing review of research that otherwise</u> | **[46.115]** (a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:<br><br>(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, |

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| | documents, progress reports submitted by investigators, and reports of injuries to subjects.<br>(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.<br>(3) Records of continuing review activities.<br>(4) Copies of all correspondence between the IRB and the investigators.<br>(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.<br>(6) Written procedures for the IRB as required by § 56.108 (a) and (b). | would not require continuing review as described in §56.109(g).<br>…<br>(5) A list of IRB members in the same detail as 56.108(a)(2).<br>(6) (6) Written procedures for the IRB as required by 56.108(a)(3) and (4).<br>(b) The records required by this regulation shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.<br>**ADDED** new paragraph 56.115(a)(8), which is consistent with the revised Common Rule's requirements at 45 CFR 46.103(e) and 45 CFR 46.115(a)(9).<br>**(a)(8)** For research that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, documentation specifying the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this part (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive | progress reports submitted by investigators, and reports of injuries to subjects.<br>(2) Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.<br>(3) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in § 46.109(f)(1).<br>(4) Copies of all correspondence between the IRB and the investigators.<br>(5) A list of IRB members in the same detail as described in § 46.108(a)(2).<br>(6) Written procedures for the IRB in the same detail as described in § 46.108(a)(3) and (4).<br>(7) Statements of significant new findings provided to subjects, as required by § 46.116(c)(5).<br>(8) The rationale for an expedited reviewer's determination under § 46.110(b)(1)(i) that research appearing on the expedited review list described in § 46.110(a) is more than minimal risk. Note: This is not included in the current FDA proposals. FDA proposes to **maintain** the requirement that the reviewer determine that the research involves no more than minimal risk. |

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| | (7) Statements of significant new findings provided to subjects, as required by § 50.25.<br><br>(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.<br><br>(c) The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection under this section. Note: This is not included in the Common Rule. | providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol). | (9) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in § 46.103(e).<br><br>(b) The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner. |
| DEFINITIONS | For all FDA Definitions, see 50.3 and 56.102.<br><br>The following FDA definitions do not have comparable terms defined in the Common Rule (45 CFR 46): *Act, Application for research or marketing permit, Emergency use, Sponsor, Sponsor-investigator, Test article, Family member, Ward*. | **MODIFIED**<br><br>Modified 50.3(b)(16) through (19) by adding "of the Federal Food, Drug, and Cosmetic Act" at the end of each sentence.<br><br>Modified 50.3(b)(20) and 56.102(b)(17) by removing "section 358 of the Public Health Service Act" and adding in its place "section 534 of the Federal Food, Drug, and Cosmetic Act". | For all Common Rule Definitions, see 46.102.<br><br>**FDA is proposing to add the following revised Common Rule definitions:** *Written or in writing, Private information, Identifiable private information, Identifiable private biospecimen.* Other Common Rule definitions that do not have comparable terms defined in 21 CFR 50 or 56: *Certification, Department or agency head, Federal department or agency, Intervention, Interaction, IRB approval, Public health authority.* |
| DEFINITION OF ACT | **[50.3(a) and 56.102(a)]** *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-902, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 321-392)). | **REMOVED** and reserved paragraph (a) | N/A |

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| DEFINITION OF RESEARCH | Note: FDA has defined "clinical research" to be synonymous with "research".<br><br>**[56.102(c)]** *Clinical Investigation* means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies. The terms *research, clinical research, clinical study, study,* and *clinical investigation* are deemed to be synonymous for purposes of this part. | N/A | **[46.102(l)]** *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research: …<br>Note: A list of activities deemed not to be research is not included in the current FDA proposals. See 46.102(l) for complete text. |
| DEFINITION OF HUMAN SUBJECT | **[21 CFR 56.102(e)]** *Human subject* means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.<br><br>**[21 CFR 812.3(p)]** *Subject* means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease. | N/A | **[46.102(e)]** Human subject means a living individual about whom an investigator (whether professional or student) conducting research:<br><br>(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or<br><br>(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. |

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| | **Importantly, FDA definitions of *human subject* do not differentiate between identifiable and non-identifiable specimens or data.** | | |
| DEFINITION OF WRITTEN OR IN WRITING | N/A | **ADDED 50.3(t) and 56.102(n)**<br>*Written or in writing* means writing on a tangible medium (e.g., paper) or in an electronic format. | **[46.102(m)]** *Written, or in writing*, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format. |
| DEFINITION OF PRIVATE INFORMATION | N/A | **ADDED 50.3(u)**<br>*Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). | **[46.102(e)(4)]** *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). |
| DEFINITION OF IDENTIFIABLE PRIVATE INFORMATION | N/A | **ADDED 50.3(v)**<br>*Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the sponsor or investigator or associated with the information. | **[46.102(e)(5)]** *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. |
| DEFINITION OF IDENTIFIABLE BIOSPECIMEN | N/A | **ADDED 50.3(w)**<br>*Identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the sponsor or investigator or associated with the biospecimen. | **[46.102(e)(6)]** *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. |

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| DEFINITION OF INSTITUTIONAL REVIEW BOARD | **[50.3(i)]** *Institutional review board* (IRB) means any board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of and conduct periodic review of such research. The term has the same meaning as the phrase institutional review committee as used in section 520(g) of the act. | **MODIFIED 50.3(i)** to read:<br><br>*Institutional review board (IRB)* means any board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, and to approve the initiation of and conduct periodic review of such research. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase institutional review committee as used in section 520(g) of the Federal Food, Drug, and Cosmetic Act ~~act~~. | **[46.102(g)]** *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy. |
| DEFINITION OF TEST ARTICLE | **[50.3(j)]** *Test article* means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).<br><br>**[56.102(l)]** *Test article* means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act. | **MODIFIED 50.3(j)** to read:<br><br>*Test article* means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act ~~act~~ or under section~~s~~ 351 ~~and 354-360F~~ of the Public Health Service Act (42 U.S.C. 262 ~~and 263b-263n~~).<br><br>**MODIFIED 56.102(l)** to read**:**<br><br>*Test article* means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act ~~act~~ or under section~~s~~ 351 ~~or 354-360F~~ of the Public Health Service Act (42 USC 262). | N/A |

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| DEFINITION OF A CLINICAL TRIAL (CLINICAL INVESTIGATION) | *Clinical Trial* means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA…or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. (See Definition of Research for full definition) | N/A | **[46.102(b)]** *Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. |
| DEFINITION OF LEGALLY AUTHORIZED REPRESENTATIVE | **[50.3(l)]** *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. | **MODIFIED 50.3(l)** to read:<br><br>*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. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research. | **[46.103(i)]** *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. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research. |
| EMERGENCY USE, EXPANDED ACCESS | **[50.25(e)]** Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.<br><br>Summary of other provisions:<br><br>FDA provides an exemption from the prospective IRB review requirement for the emergency use of a test | **MODIFIED 20.25(e):**<br><br>**50.25(e)** *Emergency medical care.* Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe). | **[46.116(j)]** *Emergency medical care.* Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe). |

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| | article in specific situations provided such use is reported to the IRB within 5 days. **[21 CFR 56.102(d) and 56.104(c)]**<br><br>FDA provides an exception from the prospective IRB review requirement for the use of a Humanitarian Use Device (HUD) when approval from an IRB cannot be obtained in time to prevent serious harm or death, such uses must be reported to the IRB within 5 days. **[21 CFR 814.124]**<br><br>FDA provides for review by the IRB Chairperson (or designated IRB member) in lieu of convened IRB review for single-patient expanded access (always for devices, when requested for drugs). | | |
| EXEMPT RESEARCH | **[56.104]** The following categories of clinical investigations are exempt from the requirements of this part for IRB review:<br><br>(a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.<br><br>(b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.<br><br>(c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 | N/A | **46.104** Common Rule regulations for Exempt Research differ from 56.104. The only similarity is the exemption for taste and food quality evaluations and consumer acceptance studies. See 45 CFR 46.104 for complete text. Common Rule exempt categories are summarized here.<br><br>(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices.<br><br>(2) Certain research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior.<br><br>(3) Certain research involving benign behavioral interventions in conjunction with the collection of |

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| | working days. Any subsequent use of the test article at the institution is subject to IRB review.<br><br>(d) Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. | | information from an adult subject if the subject prospectively agrees to the procedures.<br><br>(4) Certain secondary research uses of identifiable private information or identifiable biospecimens.<br><br>(5) Research and demonstration projects that are conducted or supported by a Federal department or agency and are designed to study, evaluate, improve, or otherwise examine public benefit or service programs.<br><br>(6) Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.<br><br>(7) Storage or maintenance for secondary research for which broad consent is required.<br><br>(8) Secondary research for which broad consent is required. |

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| INFORMED CONSENT GENERAL REQUIREMENTS | **[50.20]** Except as provided in 50.22, 50.23, and 50.24, 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. 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. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. 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. | **MODIFIED 50.20** add new paragraphs (d) through (e), which would, among other things, require informed consent to begin with a concise and focused presentation of "key information" and would require informed consent information to be organized and presented in certain ways. Changes were made to redesignate and make minor editorial changes, including adding "legally authorized" representative throughout.<br><br>**50.20** Except as provided in 50.22, 50.23, and 50.24:<br><br>(a) Before involving~~, no investigator may involve~~ a human ~~being as a~~ subject in research covered by these regulations, ~~unless~~ the investigator shall obtain ~~has obtained~~ the legally effective informed consent of the subject or the subject's legally authorized representative.<br><br>(b) An investigator shall seek informed ~~such~~ 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.<br><br>(c) The information that is given to the subject or the legally authorized representative shall be in language | Common Rule paragraph **46.116(a)** includes a general summary of informed consent requirements described in (b)-(f). See full text at 46.116(a).<br><br>Except as provided elsewhere in this policy:<br><br>(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.<br>(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.<br>(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.<br>(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.<br>(5) Except for broad consent obtained in accordance with paragraph (d) of this section: Note: Broad |

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| | | understandable to the subject or the legally authorized representative.<br><br>**ADDED** new paragraphs **50.20(d), (e)(1), and (e)(2):**<br><br>(d) 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.<br><br>(e)(1) 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.<br><br>(e)(2) 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. | consent is not included in the current FDA proposals.<br>(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.<br>(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.<br>(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 releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. |

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| | | **MODIFIED 50.20(f)** to read**:**<br><br>(f) No informed consent~~, whether oral or written,~~ 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 releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. | |
| INFORMED CONSENT BASIC ELEMENTS OF CONSENT REQUIREMENTS | **[50.25(a)]** Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:<br><br>(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 which are experimental.<br>(2) A description of any reasonably foreseeable risks or discomforts to the subject.<br>(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.<br>(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.<br>(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained *and that notes* | **MODIFIED 50.25(a)** to add a new basic element of informed consent at (a)(9) and made minor editorial changes, including adding "legally authorized" representative throughout.<br><br>(a) Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject or legally authorized representative:<br><br>…<br><br>(3) A description of any benefits to the subject or to others that ~~which~~ may reasonably be expected from the research.<br><br>**ADDED 50.25(a)(9):**<br><br>(9) A description of how information or biospecimens may be used for future research or distributed to another investigator for future research. | **[46.116(b)]** Basic elements of informed consent. Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:<br><br>(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;<br>(2) A description of any reasonably foreseeable risks or discomforts to the subject;<br>(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;<br>(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; |

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| | *the possibility that the Food and Drug Administration may inspect the records.* Note: The italicized text is not included in the Common Rule.<br>(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.<br>(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.<br>(8) A statement that participation is voluntary, that refusal to participate will involve 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. | | (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;<br>(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;<br>(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;<br>(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<br>(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: See 45 CFR 46.116(b)(9) for complete text. While FDA is not proposing to use language verbatim from the revised Common Rule for this new basic element of informed consent at 50.25(a)(9), FDA's proposal similarly requires the provision of additional information |

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| | | | to potential subjects about the possible future use of their information or biospecimens. |
| INFORMED CONSENT – ADDITIONAL ELEMENTS | **[50.25(b)]** Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:<br>(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.<br>(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.<br>(3) Any additional costs to the subject that may result from participation in the research.<br>(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.<br>(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.<br>(6) The approximate number of subjects involved in the study. | **MODIFIED 50.25(b) and 50.25(c)** to add new additional elements of informed consent at (b)(7) through (9) and make minor editorial changes, including adding "legally authorized" representative throughout.<br>**MODIFIED** (b), (b)1, (b)2, and (b)5:<br>(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject or legally authorized representative:<br>(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 ~~which~~ are currently unforeseeable.<br>(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or legally authorized representative's consent.<br>…<br>(5) A statement that significant new findings developed during the course of the research that ~~which~~ may relate to the subject's willingness to continue participation will be provided to the subject. | **[46.116(c)]** Additional elements of informed consent. Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:<br>(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;<br>(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;<br>(3) Any additional costs to the subject that may result from participation in the research;<br>(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;<br>(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;<br>(6) The approximate number of subjects involved in the study; |

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| | **[50.25(c)]** When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time." Note: 50.25(c) is not included in the Common Rule. | **ADDED** (b)(7), (8) and (9):<br>(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;<br>(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<br>(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).<br>**MODIFIED** 50.25(c): To add paragraph heading "*Required statement in informed consent documents for applicable clinical trials.**" | (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;<br>(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<br>(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). |
| INFORMED CONSENT PREEMPTIONS | **[50.25(d)]** The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective. | **MODIFIED 50.25(d):**<br>(d) *Preemption*. The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) which require additional information to be disclosed for informed consent to be legally effective. | **[46.116(i)]** Preemption. The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective. |

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| WAIVER OR ALTERATION OF INFORMED CONSENT | **[50.22]** Exception from informed consent requirements for minimal risk clinical investigations: The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent set forth in § 50.25(a) and (b), or may waive the requirement to obtain informed consent, provided the IRB finds and documents the following:<br><br>(a) The clinical investigation involves no more than minimal risk to the subjects;<br><br>(b) The clinical investigation could not practicably be carried out without the requested waiver or alteration;<br><br>(c) If the clinical investigation involves using identifiable private information or identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format;<br><br>(d) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and<br><br>(e) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.<br><br>**[50.23(a)-(c)] Emergency Exception:** | N/A | **[46.116(e)]** Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials. Note: This is not included in FDA regulations. See 46.116(e) for complete text.<br><br>**[46.116(f)]** General waiver or alteration of consent<br><br>(1) Waiver. An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens. Note: Broad consent is not included in the current FDA proposals.<br>(2) Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent |

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| | (a) The obtaining of 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:<br>(1) The human subject is confronted by a life-threatening situation necessitating the use of the test article.<br>(2) Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.<br>(3) Time is not sufficient to obtain consent from the subject's LAR.<br>(4) There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.<br>(b) If immediate use of the test article is, in the investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination required in paragraph (a) of this section in advance of using the test article, the determinations of the clinical investigator shall be made and, within 5 working days after the use of the article, be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. | | procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section. Note: Broad consent is not included in the current FDA proposals.<br>(3) Requirements for waiver and alteration. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:<br>(i) The research involves no more than minimal risk to the subjects;<br>(ii) The research could not practicably be carried out without the requested waiver or alteration;<br>(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;<br>(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and<br>(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.<br>**Secretarial Waiver for Planned Emergency Research:** In 1996 (Federal Register, Vol. 61, pp. 51531-51533), the Secretary of HHS, announced a waiver of the applicability of requirement for obtaining and |

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| | (c) The documentation required in paragraph (a) or (b) of this section shall be submitted to the IRB within 5 working days after the use of the test article.<br><br>Note: The 50.23(a)-(c) Emergency Exception is not included in the Common Rule.<br><br>**50.23(d) Presidential Waiver:** This section outlines the extensive requirements for a presidential waiver of the prior consent requirement for members of the armed forces in connection with the member's participation in a military operation. See 21 CFR 50.23(d) for regulatory text. Note: The 50.23(d) Presidential Waiver is not included in the Common Rule.<br><br>**50.23(e) In Vitro Diagnostic Devices Exception:** This section outlines the requirements for an exception of the requirement for informed consent for the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents in certain circumstances. See 21 CFR 50.23(e) for regulatory text. Note: The 50.23(e) IDE Exception is not included in the Common Rule.<br><br>**50.24 Planned Emergency Research Exception:** This section outlines the extensive requirements for approval of an investigation in an emergency setting without requiring informed consent of all research subjects. The FDA exception from informed consent requirements for emergency research permits planned research in an emergency setting when human subjects who are in need of emergency | | documenting informed consent for a strictly limited class of research, involving research activities that may be carried out in human subjects who are in need of emergency therapy and for whom, because of the subjects' medical condition and the unavailability of LARs of the subjects, no legally effective informed consent can be obtained. The waiver is consistent with the FDA's regulations on this topic at 21 CFR 50.24 with the following exceptions:<br><br>1. The Secretarial waiver does not apply to research involving fetuses, pregnant women, and human in vitro fertilization nor to research involving prisoners<br>2. The Secretarial waiver defers to the FDA regulation when the research is subject to FDA regulations<br>3. The IRB must report to OHRP that it has determined that the conditions of the Secretarial waiver have been met for the research<br>4. The Secretarial waiver does not include the requirement for concurrence by a licensed physician<br>5. The Secretarial waiver defines "family member" for the purposes of the waiver as "any one of the following legally competent persons: spouses, 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."<br>6. The Secretarial Waiver does not include the FDA's record retention requirement or statement regarding FDA's access to inspect and copy records |

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| | medical intervention cannot provide legally effective informed consent themselves, and there is generally insufficient time and opportunity to locate and obtain consent from their legally authorized representatives. See 21 CR 50.24 for regulatory text. Note: The 50.24 Planned Emergency Research Exception is not included in the Common Rule, however, this topic is addressed in the *1996 Secretarial Waiver for Planned Emergency Research*. See the DHHS Regulations column for more information. | | 7. The Secretarial Waiver does not include the FDA's requirement for a separate IND or IDE<br>8. The Secretarial Waiver does not include the FDA's requirement for prompt written notification to the investigator or sponsor if an IRB determines that it cannot approve the research because the conditions of the waiver aren't satisfied or because of other relevant ethical concerns. Nor does it include the subsequent requirement that the sponsor promptly disclose this information to the FDA, other investigators, and other IRBs. |
| SCREENING, RECRUITMENT, OR DETERMINING ELIGIBILITY | N/A<br><br>The FDA already allows for such activities because they do not consider them to be part of the clinical investigation. For more information, see the proposed rule, FDA Guidance on Informed Consent (Section V, #15), and FDA's Information Sheet on Screening Tests Prior to Study Enrollment. | N/A | **[46.116(g)]** Screening, recruiting, or determining eligibility. Note: This is not included in the current FDA proposals. See 46.116(g) for complete text. |
| DOCUMENTATION OF INFORMED CONSENT | **[50.27]** (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 signed *and dated* by the subject or the subject's legally authorized representative *at the time of consent*. A copy shall be given to the person signing the form. Note: Italicized text is not included in the Common Rule.<br><br>(b) Except as provided in 56.109(c), the consent form may be either of the following: | **MODIFIED 50.27** to read:<br><br>(a) Except as provided in 56.109(c) of this chapter, informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated (including in an electronic format) by the subject or the subject's legally authorized representative at the time of consent. A written copy shall be given to the person signing the informed consent form. | **[46.117]** (a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.<br><br>(b) Except as provided in paragraph (c) of this section, the informed consent form may be either of the following: |

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| | (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.<br>(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. When this method is used, there shall be a witness to the oral 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.<br><br>**Note**: FDA's Information Sheet on Informed Consent indicates the following when the short form is used for a subject with limited English proficiency (LEP) instead of a translated long form: | (b) Except as provided in 56.109(c) of this chapter, the consent form may be either of the following:<br>(1) A written informed consent form ~~document~~ that meets the requirements of this part. ~~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 subject's legally authorized representative adequate opportunity to read the informed consent form ~~it~~ before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.<br>(2) A short form written informed consent form ~~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. The key information required by § 50.20 must be presented first to the subject or the subject's legally authorized representative, before other information, if any, is provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. ~~Also, the IRB shall approve a written summary of what is to be~~ | (1) A written informed consent form that meets the requirements of 46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.<br>(2) A short form written informed consent form stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by § 46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form. |

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| | "The investigator must obtain a translated copy of the IRB-approved English version of the long form that served as the written summary, which should be done promptly. The investigator promptly submits it to the IRB for review and approval. Once the translated long form/written summary is approved by the IRB, the investigator must provide it to the subject or LAR and should do so as soon as possible. FDA considers this step essential to the requirement that informed consent be documented by the use of a written consent document and that the subject be provided a copy (21 CFR 50.27). Many of the clinical investigations regulated by FDA involve ongoing interventions and may involve long-term follow-up. For this reason, translation of the long form is critically important as a means of providing subjects or their LAR an ongoing source of information understandable to them." | ~~said to the subject or the representative.~~ Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form. | |
| WAIVER OF DOCUMENTATION OF INFORMED CONSENT | **[56.109(c)]** An IRB shall require documentation of informed consent in accordance with § 50.27 of this chapter, except as follows:<br>(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 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 | **ADDED** new paragraph (c)(3) to add an exception to the requirement for documentation of informed consent, to harmonize with the revised Common Rule at 46.117 (c)(1)(iii).<br>**(c)(3)** The IRB may waive documentation of informed consent if it finds that the subjects or legally authorized representative are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects, and provided | **[46.117(c)]**<br>(1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:<br>(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation |

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| | (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.<br><br>**[56.109(d)]** 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. | there is an appropriate alternative mechanism for documenting that informed consent was obtained. | linking the subject with the research, and the subject's wishes will govern; Note: This is not included in the current FDA proposals.<br>(ii) 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; or<br>(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.<br>(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research. |
| WAIVER OF PARENTAL OR GUARDIAN PERMISSION | [50.55(e)] In addition to the determinations required under other applicable sections of this subpart D, the IRB must determine, *in accordance with and to the extent that consent is required under part 50*, that the permission of each child's parents or guardian is granted. | N/A | 46.408(c) describes that the IRB may waive the requirement for parental or guardian permission if:<br>1. The research meets the criteria for a waiver of consent in 46.116<br>2. The research is designed for conditions or a population for which parent/guardian permission is not a reasonable requirement to protect the subjects (examples include neglected |

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| | (Criteria for a waiver of consent are described in 50.22.) | | and abused children) provided that an appropriate mechanism for protecting the children who will participate is substituted and that the waiver is not inconsistent with other law. Note: FDA regulations do **not** include this provision.<br><br>**Note:** Subpart D is not part of the Common Rule (Subpart A) but is included here for the comparison to FDA regulations. |
| POSTING OF CLINICAL TRIAL CONSENT FORMS | N/A | N/A | **[46.116(h)]** Posting of clinical trial consent form. Note: This is not included in the current FDA proposals. |
| COOPERATIVE RESEARCH (SINGLE IRB REVIEW) | **[56.114]** In complying with these regulations, institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort. | **MODIFIED 56.114** to read:<br><br>(a) Cooperative research covered by these regulations is a clinical investigation that involves more than one institution. In the conduct of cooperative research, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with these regulations.<br><br>(b)<br><br>(1) Any institution located in the United States that is participating in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. | **[46.114]** (a) Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.<br><br>(b)<br><br>(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. *The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the* |

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| | | (2) Research is not subject to paragraph (b)(1) of this section if at least one of the following criteria is met:<br>(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe);<br>(ii) Cooperative research involving a highly specialized FDA-regulated medical product for which unique, localized expertise is required;<br>(iii) Cooperative research on drugs that meets the exemptions from an investigational new drug application under § 312.2(b) of this chapter; or<br>(iv) Cooperative research on medical devices that meets the abbreviated requirements under § 812.2(b) of this chapter, or that meets the requirements for exempted investigations under § 812.2(c) of this chapter.<br><br>(c) For research not subject to paragraph (b) of this section, an institution participating in cooperative research may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort. | *research.* Note: The italicized text is not included in the current FDA proposals.<br>(2) The following research is not subject to this provision:<br>(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or<br>(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context. Note: This is not included in the current FDA proposals. FDA proposes different exclusions in 2(ii), (iii), and (iv).<br><br>(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort. |

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| REVIEW BY INSTITUTION | **[56.112]** Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB. | N/A | **[46.112]** Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB. |
| SUSPENSION OR TERMINATION OF IRB APPROVAL OF RESEARCH | **[56.113]** An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration. | N/A | **[46.112]** An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head. |
| ADMINISTRATIVE ACTIONS FOR NONCOMPLIANCE | **21 CFR 56 Subpart E** outlines Administrative Actions for Noncompliance. Sections include:<br>56.120 Lesser administrative actions.<br>56.121 Disqualification of an IRB or an institution.<br>56.122 Public disclosure of information regarding revocation.*<br>56.123 Reinstatement of an IRB or an institution.*<br>56.124 Actions alternative or additional to disqualification.<br>*There are no comparable provisions in 45 CFR 46.<br><br>See Subpart E for full text. Below are sections impacted by the proposed rule.<br><br>**56.121 Disqualification of an IRB or an institution.** | **MODIFIED 56.121(c)** so the last sentence reads**:**<br><br>(c) …In addition, the agency may elect to publish a notice of its action ~~in the Federal Register~~.<br><br>**MODIFIED 56.122:**<br><br>Modify section title from “revocation” to “disqualification”.<br><br>A determination that ~~the Food and Drug Administration~~ FDA has disqualified an IRB or an institution and the administrative record regarding that determination are disclosable to the public under part 20 of this chapter. | **45 CFR 46** includes the following sections:<br>46.123 Early termination of research support: Evaluation of applications and proposals.<br>46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.<br>46.122 Use of Federal funds.<br>46.124 Conditions. |

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| | **(c)** If the Commissioner determines that disqualification is appropriate, the Commissioner will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing clinical research conducted under the review of the IRB. The Food and Drug Administration will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and clinical investigators, may also be sent a notice of the disqualification. In addition, the agency may elect to publish a notice of its action in the Federal Register.<br><br>**[56.122] Public disclosure of information regarding revocation.** A determination that the Food and Drug Administration has disqualified an institution and the administrative record regarding that determination are disclosable to the public under part 20. | | |

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| PART 812 INVESTIGATIONAL DEVICE EXEMPTIONS: REPORTS | **[812.150]** (a) Investigator reports. An investigator shall prepare and submit the following complete, accurate, and timely reports:<br>…<br>(3) Progress. An investigator shall submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.<br>(b) Sponsor reports. A sponsor shall prepare and submit the following complete, accurate, and timely reports:<br>…<br>(5) Progress reports. At regular intervals, and at least yearly, a sponsor shall submit progress reports to all reviewing IRB's. In the case of a significant risk device, a sponsor shall also submit progress reports to FDA. A sponsor of a treatment IDE shall submit semi-annual progress reports to all reviewing IRB's and FDA in accordance with § 812.36(f) and annual reports in accordance with this section. | **MODIFIED 812.150** to read**:**<br>(a)(3) Progress. An investigator shall submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly. Such progress reports shall be submitted to the reviewing IRB to the extent that continuing review is required by part 56 of this chapter.<br>(b)(5) Progress reports. At regular intervals, and at least yearly, a sponsor shall submit progress reports to all reviewing IRBs. Such progress reports shall be submitted to reviewing IRBs to the extent required by part 56 of this chapter. In the case of a significant risk device, a sponsor shall ~~also~~ submit progress reports to FDA at regular intervals, and at least yearly. A sponsor of a treatment IDE shall submit semiannual progress reports to all reviewing IRBs and FDA in accordance with § 812.36(f) and annual progress reports in accordance with this section. | N/A |