



# GCP Compliance Checklist

## Good Clinical Practices (GCP)

Good Clinical Practices (GCP) refers to the regulations and requirements that must be complied with while conducting a clinical study. These regulations that apply to the manufacturers, sponsors, clinical investigators, institutional review boards, and the medical device. The primary regulations that govern the conduct of clinical studies are included in the Code of Federal Regulations, Title 21 (21 CFR):

- 21 CFR 812, [Investigational Device Exemptions](#), covers the procedures for the conduct of clinical studies with medical devices including application, responsibilities of sponsors and investigators, labeling, records, and reports.
- 21 CFR 50, [Protection of Human Subjects](#), provides the requirements and general elements of informed consent;
- 21 CFR 56, [Institutional Review Boards](#), covers the procedures and responsibilities for institutional review boards (IRBs) that approve clinical investigations protocols;
- 21 CFR 54, [Financial Disclosure by Clinical Investigators](#), covers the disclosure of financial compensation to clinical investigators which is part of FDA's assessment of the reliability of the clinical data.
- 21 CFR 820 Subpart C, [Design Controls of the Quality System Regulation](#), provides the requirement for procedures to control the design of the device in order to ensure that the specified design requirements are met.

Reg#	Requirement	Yes	N/A	Requires Action	Notes
<b>Part 812 Investigational Device Exemptions</b>					
812.5(a)	Contents. An investigational device or its immediate package shall bear a label with the following information: the name and place of business of the manufacturer, packer, or distributor (in accordance with § 801.1), the quantity of contents, if appropriate, and the following statement: "CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use." The label or other labeling shall describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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812.5(b)	Prohibitions. The labeling of an investigational device shall not bear any statement that is false or misleading in any particular and shall not represent that the device is safe or effective for the purposes for which it is being investigated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.5(c)	Animal research. An investigational device shipped solely for research on or with laboratory animals shall bear on its label the following statement: "CAUTION—Device for investigational use in laboratory animals or other tests that do not involve human subjects."	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.7(a)	A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:  Promote or test market an investigational device, until after FDA has approved the device for commercial distribution.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.7(b)	A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:  Commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.7(c)	A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:  Unduly prolong an investigation. If data developed by the investigation indicate in the case of a class III device that premarket approval cannot be justified or in the case of a class II device that it will not comply with an applicable performance standard or an amendment to that standard, the sponsor shall promptly terminate the investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.7(d)	A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:  Represent that an investigational device is safe or effective for the purposes for which it is being investigated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.10(a)	A sponsor may request FDA to waive any requirement of this part. A waiver request, with supporting documentation,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	may be submitted separately or as part of an application to the address in § 812.19.				
812.10(b)	FDA action. FDA may by letter grant a waiver of any requirement that FDA finds is not required by the act and is unnecessary to protect the rights, safety, or welfare of human subjects.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.10(c)	Effect of request. Any requirement shall continue to apply unless and until FDA waives it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.18(a)	Imports. In addition to complying with other requirements of this part, a person who imports or offers for importation an investigational device subject to this part shall be the agent of the foreign exporter with respect to investigations of the device and shall act as the sponsor of the clinical investigation, or ensure that another person acts as the agent of the foreign exporter and the sponsor of the investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.18(b)	Exports. A person exporting an investigational device subject to this part shall obtain FDA's prior approval, as required by section 801(e) of the act or comply with section 802 of the act.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.19	If you are sending an application, supplemental application, report, request for waiver, request for import or export approval, or other correspondence relating to matters covered by this part, you must address it to the Center for Devices and Radiological Health, Document Mail Center (HFZ-401), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850. You must state on the outside wrapper of each submission what the submission is, for example, an "IDE application," a "supplemental IDE application," or a "correspondence concerning an IDE (or an IDE application)."	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(a)(1)	A sponsor shall submit an application to FDA if the sponsor intends to use a significant risk device in an investigation, intends to conduct an investigation that involves an exception from informed consent under § 50.24 of this chapter, or if FDA notifies the sponsor that an application is required for an investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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812.20(a)(2)	A sponsor shall not begin an investigation for which FDA's approval of an application is required until FDA has approved the application.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(a)(3)	A sponsor shall submit three copies of a signed "Application for an Investigational Device Exemption" (IDE application), together with accompanying materials, by registered mail or by hand to the address in § 812.19. Subsequent correspondence concerning an application or a supplemental application shall be submitted by registered mail or by hand.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(a)(4)(i)	A sponsor shall submit a separate IDE for any clinical investigation involving an exception from informed consent under § 50.24 of this chapter. Such a clinical investigation is not permitted to proceed without the prior written authorization of FDA. FDA shall provide a written determination 30 days after FDA receives the IDE or earlier.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(a)(4)(ii)	If the investigation involves an exception from informed consent under § 50.24 of this chapter, the sponsor shall prominently identify on the cover sheet that the investigation is subject to the requirements in § 50.24 of this chapter.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(b)(1)	An IDE application shall include, in the following order:  (1) The name and address of the sponsor,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(b)(2)	(2) A complete report of prior investigations of the device and an accurate summary of those sections of the investigational plan described in § 812.25(a) through (e) or, in lieu of the summary, the complete plan. The sponsor shall submit to FDA a complete investigational plan and a complete report of prior investigations of the device if no IRB has reviewed them, if FDA has found an IRB's review inadequate, or if FDA requests them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(b)(3)	(3) A description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with good	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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	manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device.				
812.20(b)(4)	(4) An example of the agreements to be entered into by all investigators to comply with investigator obligations under this part, and a list of the names and addresses of all investigators who have signed the agreement.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(b)(5)	(5) A certification that all investigators who will participate in the investigation have signed the agreement, that the list of investigators includes all the investigators participating in the investigation, and that no investigators will be added to the investigation until they have signed the agreement.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(b)(6)	(6) A list of the name, address, and chairperson of each IRB that has been or will be asked to review the investigation and a certification of the action concerning the investigation taken by each such IRB.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(b)(7)	(7) The name and address of any institution at which a part of the investigation may be conducted that has not been identified in accordance with paragraph (b)(6) of this section.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(a)(8)	If the device is to be sold, the amount to be charged and an explanation of why sale does not constitute commercialization of the device.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(a)(9)	A claim for categorical exclusion under § 25.30 or 25.34 or an environmental assessment under § 25.40.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(a)(10)	Copies of all labeling for the device.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(a)(11)	Copies of all forms and informational materials to be provided to subjects to obtain informed consent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(a)(12)	Any other relevant information FDA requests for review of the application.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.20(c)	Additional information. FDA may request additional information concerning an investigation or revision in the investigational plan. The sponsor may treat such a request as a disapproval of the application for purposes of requesting a hearing under part 16.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



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812.20(d)	Information previously submitted. Information previously submitted to the Center for Devices and Radiological Health in accordance with this chapter ordinarily need not be resubmitted, but may be incorporated by reference.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.25(a)	The investigational plan shall include, in the following order:  The name and intended use of the device and the objectives and duration of the investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.25(b)	The investigational plan shall include :  A written protocol describing the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.25(c)	The investigational plan shall include :  A description and analysis of all increased risks to which subjects will be exposed by the investigation; the manner in which these risks will be minimized; a justification for the investigation; and a description of the patient population, including the number, age, sex, and condition.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.25(d)	The investigational plan shall include :  A description of each important component, ingredient, property, and principle of operation of the device and of each anticipated change in the device during the course of the investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.25(e)	The investigational plan shall include :  The sponsor`s written procedures for monitoring the investigation and the name and address of any monitor.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.25(f)	The investigational plan shall include :  Copies of all labeling for the device.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.25(g)	The investigational plan shall include :  Copies of all forms and informational materials to be provided to subjects to obtain informed consent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



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812.25(h)	The investigational plan shall include :  A list of the names, locations, and chairpersons of all IRB`s that have been or will be asked to review the investigation, and a certification of any action taken by any of those IRB`s with respect to the investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.25(i)	The investigational plan shall include :  The name and address of each institution at which a part of the investigation may be conducted that has not been identified in paragraph (h) of this section.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.25(j)	The investigational plan shall include :  A description of records and reports that will be maintained on the investigation in addition to those prescribed in subpart G.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.27(a)	The investigational plan shall include :  The report of prior investigations shall include reports of all prior clinical, animal, and laboratory testing of the device and shall be comprehensive and adequate to justify the proposed investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.27(b)(1)	The report also shall include:  A bibliography of all publications, whether adverse or supportive, that are relevant to an evaluation of the safety or effectiveness of the device, copies of all published and unpublished adverse information, and, if requested by an IRB or FDA, copies of other significant publications.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.27(b)(2)	Specific contents. The report also shall include:  A summary of all other unpublished information (whether adverse or supportive) in the possession of, or reasonably obtainable by, the sponsor that is relevant to an evaluation of the safety or effectiveness of the device.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.27(b)(3)	Specific contents. The report also shall include:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



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	<p>If information on nonclinical laboratory studies is provided, a statement that all such studies have been conducted in compliance with applicable requirements in the good laboratory practice regulations in part 58, or if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with this requirement does not justify failure to provide information on a relevant nonclinical test study.</p>				
<p>812.30(a)(1) 812.30(a)(2)</p>	<p>Approval or disapproval. FDA will notify the sponsor in writing of the date it receives an application. FDA may approve an investigation as proposed, approve it with modifications, or disapprove it. An investigation may not begin until:</p> <p>Thirty days after FDA receives the application at the address in § 812.19 for the investigation of a device other than a banned device, unless FDA notifies the sponsor that the investigation may not begin; or</p> <p>FDA approves, by order, an IDE for the investigation.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>812.30(b)(1)</p>	<p>Grounds for disapproval or withdrawal. FDA may disapprove or withdraw approval of an application if FDA finds that:</p> <p>There has been a failure to comply with any requirement of this part or the act, any other applicable regulation or statute, or any condition of approval imposed by an IRB or FDA.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>812.30(b)(2)</p>	<p>Grounds for disapproval or withdrawal. FDA may disapprove or withdraw approval of an application if FDA finds that:</p> <p>The application or a report contains an untrue statement of a material fact, or omits material information required by this part.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>812.30(b)(3)</p>	<p>Grounds for disapproval or withdrawal. FDA may disapprove or withdraw approval of an application if FDA finds that:</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



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	The sponsor fails to respond to a request for additional information within the time prescribed by FDA.				
812.30(b)(4)	There is reason to believe that the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, or informed consent is inadequate, or the investigation is scientifically unsound, or there is reason to believe that the device as used is ineffective.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.30(b)(5)(i) 812.30(b)(5)(ii) 812.30(b)(5)(iii)	It is otherwise unreasonable to begin or to continue the investigation owing to the way in which the device is used or the inadequacy of:  (i) The report of prior investigations or the investigational plan;  (ii) The methods, facilities, and controls used for the manufacturing, processing, packaging, storage, and, where appropriate, installation of the device; or  (iii) Monitoring and review of the investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.30(c)	Notice of disapproval or withdrawal. If FDA disapproves an application or proposes to withdraw approval of an application, FDA will notify the sponsor in writing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.30(c)(1)	A disapproval order will contain a complete statement of the reasons for disapproval and a statement that the sponsor has an opportunity to request a hearing under part 16.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.30(c)(2)	A notice of a proposed withdrawal of approval will contain a complete statement of the reasons for withdrawal and a statement that the sponsor has an opportunity to request a hearing under part 16. FDA will provide the opportunity for hearing before withdrawal of approval, unless FDA determines in the notice that continuation of testing under the exemption will result in an unreasonable risk to the public health and orders withdrawal of approval before any hearing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.359(a)(1)	Changes in investigational plan—	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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	Changes requiring prior approval. Except as described in paragraphs (a)(2) through (a)(4) of this section, a sponsor must obtain approval of a supplemental application under § 812.30(a), and IRB approval when appropriate (see §§ 56.110 and 56.111 of this chapter), prior to implementing a change to an investigational plan. If a sponsor intends to conduct an investigation that involves an exception to informed consent under § 50.24 of this chapter, the sponsor shall submit a separate investigational device exemption (IDE) application in accordance with § 812.20(a).				
812.359(a)(2)	Changes effected for emergency use. The requirements of paragraph (a)(1) of this section regarding FDA approval of a supplement do not apply in the case of a deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such deviation shall be reported to FDA within 5-working days after the sponsor learns of it (see § 812.150(a)(4)).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.35(a)(3)	Changes effected with notice to FDA within 5 days. A sponsor may make certain changes without prior approval of a supplemental application under paragraph (a)(1) of this section if the sponsor determines that these changes meet the criteria described in paragraphs (a)(3)(i) and (a)(3)(ii) of this section, on the basis of credible information defined in paragraph (a)(3)(iii) of this section, and the sponsor provides notice to FDA within 5-working days of making these changes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.35(a)(3)(i)	Developmental changes. The requirements in paragraph (a)(1) of this section regarding FDA approval of a supplement do not apply to developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or basic principles of operation and that are made in response to information gathered during the course of an investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.35(a)(3)(ii)	Changes to clinical protocol. The requirements in paragraph (a)(1) of this section regarding FDA approval of a supplement do not apply to changes to clinical protocols that do not affect:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



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	<p>(A) The validity of the data or information resulting from the completion of the approved protocol, or the relationship of likely patient risk to benefit relied upon to approve the protocol;</p> <p>(B) The scientific soundness of the investigational plan; or</p> <p>(C) The rights, safety, or welfare of the human subjects involved in the investigation.</p>				
<p>812.35(a)(3)(iii)(A) 812.35(a)(3)(iii)(B)</p>	<p>Definition of credible information.</p> <p>Credible information to support developmental changes in the device (including manufacturing changes) includes data generated under the design control procedures of § 820.30, preclinical/animal testing, peer reviewed published literature, or other reliable information such as clinical information gathered during a trial or marketing.</p> <p>Credible information to support changes to clinical protocols is defined as the sponsor's documentation supporting the conclusion that a change does not have a significant impact on the study design or planned statistical analysis, and that the change does not affect the rights, safety, or welfare of the subjects. Documentation shall include information such as peer reviewed published literature, the recommendation of the clinical investigator(s), and/or the data gathered during the clinical trial or marketing.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>812.35(a)(3)(iv)</p>	<p>Notice of IDE change.</p> <p>Changes meeting the criteria in paragraphs (a)(3)(i) and (a)(3)(ii) of this section that are supported by credible information as defined in paragraph (a)(3)(iii) of this section may be made without prior FDA approval if the sponsor submits a notice of the change to the IDE not later than 5-working days after making the change. Changes to devices are deemed to occur on the date the device, manufactured incorporating the design or manufacturing change, is distributed to the investigator(s). Changes to a clinical protocol are deemed to occur when a clinical investigator is notified by the sponsor that the change should be</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



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	<p>implemented in the protocol or, for sponsor-investigator studies, when a sponsor-investigator incorporates the change in the protocol. Such notices shall be identified as a "notice of IDE change."</p> <p>(A) For a developmental or manufacturing change to the device, the notice shall include a summary of the relevant information gathered during the course of the investigation upon which the change was based; a description of the change to the device or manufacturing process (cross-referenced to the appropriate sections of the original device description or manufacturing process); and, if design controls were used to assess the change, a statement that no new risks were identified by appropriate risk analysis and that the verification and validation testing, as appropriate, demonstrated that the design outputs met the design input requirements. If another method of assessment was used, the notice shall include a summary of the information which served as the credible information supporting the change.</p> <p>(B) For a protocol change, the notice shall include a description of the change (cross-referenced to the appropriate sections of the original protocol); an assessment supporting the conclusion that the change does not have a significant impact on the study design or planned statistical analysis; and a summary of the information that served as the credible information supporting the sponsor's determination that the change does not affect the rights, safety, or welfare of the subjects..</p>				
<p>812.35(a)(4)(i) 812.35(a)(4)(ii) 812.35(a)(4)(iii)</p>	<p>Changes submitted in annual report. The requirements of paragraph (a)(1) of this section do not apply to minor changes to the purpose of the study, risk analysis, monitoring procedures, labeling, informed consent materials, and IRB information that do not affect:</p> <p>(i) The validity of the data or information resulting from the completion of the approved protocol, or the relationship of likely patient risk to benefit relied upon to approve the protocol;</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



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	<p>(ii) The scientific soundness of the investigational plan; or</p> <p>(iii) The rights, safety, or welfare of the human subjects involved in the investigation. Such changes shall be reported in the annual progress report for the IDE, under § 812.150(b)(5).</p>				
812.35(b)	<p>IRB approval for new facilities.</p> <p>A sponsor shall submit to FDA a certification of any IRB approval of an investigation or a part of an investigation not included in the IDE application. If the investigation is otherwise unchanged, the supplemental application shall consist of an updating of the information required by § 812.20(b) and (c) and a description of any modifications in the investigational plan required by the IRB as a condition of approval. A certification of IRB approval need not be included in the initial submission of the supplemental application, and such certification is not a precondition for agency consideration of the application. Nevertheless, a sponsor may not begin a part of an investigation at a facility until the IRB has approved the investigation, FDA has received the certification of IRB approval, and FDA, under § 812.30(a), has approved the supplemental application relating to that part of the investigation (see § 56.103(a))</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.36(b)(1) 812.36(b)(2) 812.36(b)(3) 812.36(b)(4)	<p>Criteria. FDA shall consider the use of an investigational device under a treatment IDE if:</p> <p>(1) The device is intended to treat or diagnose a serious or immediately life-threatening disease or condition;</p> <p>(2) There is no comparable or satisfactory alternative device or other therapy available to treat or diagnose that stage of the disease or condition in the intended patient population;</p> <p>(3) The device is under investigation in a controlled clinical trial for the same use under an approved IDE, or such clinical trials have been completed; and</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



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	(4) The sponsor of the investigation is actively pursuing marketing approval/clearance of the investigational device with due diligence.				
812.36(c)(i) 812.36(c)(ii) 812.36(c)(iii) 812.36(c)(iv) 812.36(c)(v) 812.36(c)(vi) 812.36(c)(vii) 812.36(c)(viii) 812.36(c)(ix) 812.36(c)(x)	<p>(c) Applications for treatment use. (1) A treatment IDE application shall include, in the following order:</p> <p>(i) The name, address, and telephone number of the sponsor of the treatment IDE;</p> <p>(ii) The intended use of the device, the criteria for patient selection, and a written protocol describing the treatment use;</p> <p>(iii) An explanation of the rationale for use of the device, including, as appropriate, either a list of the available regimens that ordinarily should be tried before using the investigational device or an explanation of why the use of the investigational device is preferable to the use of available marketed treatments;</p> <p>(iv) A description of clinical procedures, laboratory tests, or other measures that will be used to evaluate the effects of the device and to minimize risk;</p> <p>(v) Written procedures for monitoring the treatment use and the name and address of the monitor;</p> <p>(vi) Instructions for use for the device and all other labeling as required under § 812.5(a) and (b);</p> <p>(vii) Information that is relevant to the safety and effectiveness of the device for the intended treatment use. Information from other IDE's may be incorporated by reference to support the treatment use;</p> <p>(viii) A statement of the sponsor's commitment to meet all applicable responsibilities under this part and part 56 of this chapter and to ensure compliance of all participating investigators with the informed consent requirements of part 50 of this chapter;</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



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	<p>(ix) An example of the agreement to be signed by all investigators participating in the treatment IDE and certification that no investigator will be added to the treatment IDE before the agreement is signed; and</p> <p>(x) If the device is to be sold, the price to be charged and a statement indicating that the price is based on manufacturing and handling costs only.</p>				
812.36(2)(d)(1)	<p>FDA action on treatment IDE applications.</p> <p>(1) Approval of treatment IDE`s. Treatment use may begin 30 days after FDA receives the treatment IDE submission at the address specified in § 812.19, unless FDA notifies the sponsor in writing earlier than the 30 days that the treatment use may or may not begin. FDA may approve the treatment use as proposed or approve it with modifications.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>812.36(2)(d)(2)(i) 812.36(2)(d)(2)(ii) 812.36(2)(d)(2)(iii) 812.36(2)(d)(2)(iv) 812.36(2)(d)(2)(v) 812.36(2)(d)(2)(vi) 812.36(2)(d)(2)(vii) 812.36(2)(d)(2)(viii) 812.36(2)(d)(2)(ix)</p>	<p>Disapproval or withdrawal of approval of treatment IDE`s. FDA may disapprove or withdraw approval of a treatment IDE if:</p> <p>(i) The criteria specified in § 812.36(b) are not met or the treatment IDE does not contain the information required in § 812.36(c);</p> <p>(ii) FDA determines that any of the grounds for disapproval or withdrawal of approval listed in § 812.30(b)(1) through (b)(5) apply;</p> <p>(iii) The device is intended for a serious disease or condition and there is insufficient evidence of safety and effectiveness to support such use;</p> <p>(iv) The device is intended for an immediately life-threatening disease or condition and the available scientific evidence, taken as a whole, fails to provide a reasonable basis for concluding that the device:</p> <p>(A) May be effective for its intended use in its intended population; or</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	<p>(B) Would not expose the patients to whom the device is to be administered to an unreasonable and significant additional risk of illness or injury;</p> <p>(v) There is reasonable evidence that the treatment use is impeding enrollment in, or otherwise interfering with the conduct or completion of, a controlled investigation of the same or another investigational device;</p> <p>(vi) The device has received marketing approval/clearance or a comparable device or therapy becomes available to treat or diagnose the same indication in the same patient population for which the investigational device is being used;</p> <p>(vii) The sponsor of the controlled clinical trial is not pursuing marketing approval/clearance with due diligence;</p> <p>(viii) Approval of the IDE for the controlled clinical investigation of the device has been withdrawn; or</p> <p>(ix) The clinical investigator(s) named in the treatment IDE are not qualified by reason of their scientific training and/or experience to use the investigational device for the intended treatment use.</p>				
812.36(3)	Notice of disapproval or withdrawal. If FDA disapproves or proposes to withdraw approval of a treatment IDE, FDA will follow the procedures set forth in § 812.30(c).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.36(e)	Safeguards. Treatment use of an investigational device is conditioned upon the sponsor and investigators complying with the safeguards of the IDE process and the regulations governing informed consent (part 50 of this chapter) and institutional review boards (part 56 of this chapter).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.36(f)	Reporting requirements. The sponsor of a treatment IDE shall submit progress reports on a semi-annual basis to all reviewing IRB's and FDA until the filing of a marketing application. These reports shall be based on the period of time since initial approval of the treatment IDE and shall	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Reg#	Requirement	Yes	N/A	Requires Action	Notes
	include the number of patients treated with the device under the treatment IDE, the names of the investigators participating in the treatment IDE, and a brief description of the sponsor's efforts to pursue marketing approval/clearance of the device. Upon filing of a marketing application, progress reports shall be submitted annually in accordance with § 812.150(b)(5). The sponsor of a treatment IDE is responsible for submitting all other reports required under § 812.150.				
812.38(a)	Existence of IDE. FDA will not disclose the existence of an IDE unless its existence has previously been publicly disclosed or acknowledged, until FDA approves an application for premarket approval of the device subject to the IDE; or a notice of completion of a product development protocol for the device has become effective.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.38(b)(1)	Availability of summaries or data.  FDA will make publicly available, upon request, a detailed summary of information concerning the safety and effectiveness of the device that was the basis for an order approving, disapproving, or withdrawing approval of an application for an IDE for a banned device. The summary shall include information on any adverse effect on health caused by the device.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.38(b)(2)	If a device is a banned device or if the existence of an IDE has been publicly disclosed or acknowledged, data or information contained in the file is not available for public disclosure before approval of an application for premarket approval or the effective date of a notice of completion of a product development protocol except as provided in this section. FDA may, in its discretion, disclose a summary of selected portions of the safety and effectiveness data, that is, clinical, animal, or laboratory studies and tests of the device, for public consideration of a specific pending issue.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.38(b)(3)	If the existence of an IDE file has not been publicly disclosed or acknowledged, no data or information in the file are available for public disclosure except as provided in paragraphs (b)(1) and (c) of this section.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Reg#	Requirement	Yes	N/A	Requires Action	Notes
812.38(b)(4)	Notwithstanding paragraph (b)(2) of this section, FDA will make available to the public, upon request, the information in the IDE that was required to be filed in Docket Number 95S-0158 in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, for investigations involving an exception from informed consent under § 50.24 of this chapter. Persons wishing to request this information shall submit a request under the Freedom of Information Act.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.38(c)	Reports of adverse effects. Upon request or on its own initiative, FDA shall disclose to an individual on whom an investigational device has been used a copy of a report of adverse device effects relating to that use.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.38(d)	Other rules. Except as otherwise provided in this section, the availability for public disclosure of data and information in an IDE file shall be handled in accordance with § 814.9.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.40	Sponsors are responsible for selecting qualified investigators and providing them with the information they need to conduct the investigation properly, ensuring proper monitoring of the investigation, ensuring that IRB review and approval are obtained, submitting an IDE application to FDA, and ensuring that any reviewing IRB and FDA are promptly informed of significant new information about an investigation. Additional responsibilities of sponsors are described in subparts B and G.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.42	A sponsor shall not begin an investigation or part of an investigation until an IRB and FDA have both approved the application or supplemental application relating to the investigation or part of an investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.43(a)	Selecting investigators. A sponsor shall select investigators qualified by training and experience to investigate the device.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.43(b)	Control of device. A sponsor shall ship investigational devices only to qualified investigators participating in the investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.43(c)(1)	A sponsor shall obtain from each participating investigator a signed agreement that includes:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	The investigator`s curriculum vitae.				
812.43(c)(2)	A sponsor shall obtain from each participating investigator a signed agreement that includes:  Where applicable, a statement of the investigator`s relevant experience, including the dates, location, extent, and type of experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.43(c)(3)	A sponsor shall obtain from each participating investigator a signed agreement that includes:  If the investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to termination.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.43(c)(4)(i) 812.43(c)(4)(ii) 812.43(c)(4)(iii)	A sponsor shall obtain from each participating investigator a signed agreement that includes:  A statement of the investigator`s commitment to:  (i) Conduct the investigation in accordance with the agreement, the investigational plan, this part and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB or FDA;  (ii) Supervise all testing of the device involving human subjects; and  (iii) Ensure that the requirements for obtaining informed consent are met.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.43(c)(5)	A sponsor shall obtain from each participating investigator a signed agreement that includes:  Sufficient accurate financial disclosure information to allow the sponsor to submit a complete and accurate certification or disclosure statement as required under part 54 of this chapter. The sponsor shall obtain a commitment from the clinical investigator to promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following completion of the	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Reg#	Requirement	Yes	N/A	Requires Action	Notes
	study. This information shall not be submitted in an investigational device exemption application, but shall be submitted in any marketing application involving the device.				
812.43(d)	A sponsor shall select monitors qualified by training and experience to monitor the investigational study in accordance with this part and other applicable FDA regulations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.45	A sponsor shall supply all investigators participating in the investigation with copies of the investigational plan and the report of prior investigations of the device.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.46(a)	A sponsor who discovers that an investigator is not complying with the signed agreement, the investigational plan, the requirements of this part or other applicable FDA regulations, or any conditions of approval imposed by the reviewing IRB or FDA shall promptly either secure compliance, or discontinue shipments of the device to the investigator and terminate the investigator's participation in the investigation. A sponsor shall also require such an investigator to dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.46(b)(1)	A sponsor shall immediately conduct an evaluation of any unanticipated adverse device effect.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.46(b)(2)	A sponsor who determines that an unanticipated adverse device effect presents an unreasonable risk to subjects shall terminate all investigations or parts of investigations presenting that risk as soon as possible. Termination shall occur not later than 5 working days after the sponsor makes this determination and not later than 15 working days after the sponsor first received notice of the effect.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.46(c)	Resumption of terminated studies. If the device is a significant risk device, a sponsor may not resume a terminated investigation without IRB and FDA approval. If the device is not a significant risk device, a sponsor may not resume a terminated investigation without IRB approval and, if the investigation was terminated under paragraph	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Reg#	Requirement	Yes	N/A	Requires Action	Notes
	(b)(2) of this section, FDA approval.				
812.47(a)	The sponsor shall monitor the progress of all investigations involving an exception from informed consent under § 50.24 of this chapter. When the sponsor receives from the IRB information concerning the public disclosures under § 50.24(a)(7)(ii) and (a)(7)(iii) of this chapter, the sponsor shall promptly submit to the IDE file and to Docket Number 95S-0158 in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, copies of the information that was disclosed, identified by the IDE number.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.47(b)	The sponsor also shall monitor such investigations to determine when an IRB determines that it cannot approve the research because it does not meet the criteria in the exception in § 50.24(a) of this chapter or because of other relevant ethical concerns. The sponsor promptly shall provide this information in writing to FDA, investigators who are asked to participate in this or a substantially equivalent clinical investigation, and other IRB's that are asked to review this or a substantially equivalent investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.60	An IRB reviewing and approving investigations under this part shall comply with the requirements of part 56 in all respects, including its composition, duties, and functions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.62(a)	An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all investigations covered by this part.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.62(b)	If no IRB exists or if FDA finds that an IRB's review is inadequate, a sponsor may submit an application to FDA.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.64	The IRB shall conduct its continuing review of an investigation in accordance with part 56.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.66	If an IRB determines that an investigation, presented for approval under § 812.2(b)(1)(ii), involves a significant risk device, it shall so notify the investigator and, where appropriate, the sponsor. A sponsor may not begin the investigation except as provided in § 812.30(a).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.100	An investigator is responsible for ensuring that an	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of devices under investigation. An investigator also is responsible for ensuring that informed consent is obtained in accordance with part 50 of this chapter. Additional responsibilities of investigators are described in subpart G.				
812.110(a)	Awaiting approval. An investigator may determine whether potential subjects would be interested in participating in an investigation, but shall not request the written informed consent of any subject to participate, and shall not allow any subject to participate before obtaining IRB and FDA approval.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.110(b)	An investigator shall conduct an investigation in accordance with the signed agreement with the sponsor, the investigational plan, this part and other applicable FDA regulations, and any conditions of approval imposed by an IRB or FDA.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.110(c)	An investigator shall permit an investigational device to be used only with subjects under the investigator's supervision. An investigator shall not supply an investigational device to any person not authorized under this part to receive it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.110(d)	A clinical investigator shall disclose to the sponsor sufficient accurate financial information to allow the applicant to submit complete and accurate certification or disclosure statements required under part 54 of this chapter. The investigator shall promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following completion of the study.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.110(e)	Disposing of device. Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, an investigator shall return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
812.119(a)	If FDA has information indicating that an investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50, or part 56 of this chapter, or has repeatedly or deliberately submitted false information either to the sponsor of the investigation or in any required report, the Center for Devices and Radiological Health will furnish the investigator written notice of the matter under complaint and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. If an explanation is offered and accepted by the Center for Devices and Radiological Health, the disqualification process will be terminated. If an explanation is offered but not accepted by the Center for Devices and Radiological Health, the investigator will be given an opportunity for a regulatory hearing under part 16 of this chapter on the question of whether the investigator is entitled to receive investigational devices.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.119(b)	After evaluating all available information, including any explanation presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50, or part 56 of this chapter, or has deliberately or repeatedly submitted false information either to the sponsor of the investigation or in any required report, the Commissioner will notify the investigator, the sponsor of any investigation in which the investigator has been named as a participant, and the reviewing IRB that the investigator is not entitled to receive investigational devices. The notification will provide a statement of basis for such determination.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.119(c)	Each investigational device exemption (IDE) and each cleared or approved application submitted under this part, subpart E of part 807 of this chapter, or part 814 of this chapter containing data reported by an investigator who has been determined to be ineligible to receive investigational devices will be examined to determine whether the investigator has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval or clearance of any marketing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	application.				
812.119(d)	If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, the Commissioner will notify the sponsor who shall have an opportunity for a regulatory hearing under part 16 of this chapter. If a danger to the public health exists, however, the Commissioner shall terminate the IDE immediately and notify the sponsor and the reviewing IRB of the determination. In such case, the sponsor shall have an opportunity for a regulatory hearing before FDA under part 16 of this chapter on the question of whether the IDE should be reinstated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.119(e)	If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the continued clearance or approval of the marketing application for which the data were submitted cannot be justified, the Commissioner will proceed to withdraw approval or rescind clearance of the medical device in accordance with the applicable provisions of the act.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.119(f)	An investigator who has been determined to be ineligible to receive investigational devices may be reinstated as eligible when the Commissioner determines that the investigator has presented adequate assurances that the investigator will employ investigational devices solely in compliance with the provisions of this part and of parts 50 and 56 of this chapter.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.140(a)(1)	A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:  All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.140(a)(2)(i) 812.140(a)(2)(ii) 812.140(a)(2)(iii)	A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	<p>Records of receipt, use or disposition of a device that relate to:</p> <p>(i) The type and quantity of the device, the dates of its receipt, and the batch number or code mark.</p> <p>(ii) The names of all persons who received, used, or disposed of each device.</p> <p>(iii) Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.</p>				
<p>812.140(a)(3)(i) 812.140(a)(3)(ii) 812.140(a)(3)(iii)</p>	<p>A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:</p> <p>Records of each subject's case history and exposure to the device. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. Such records shall include:</p> <p>(i) Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. The case history for each individual shall document that informed consent was obtained prior to participation in the study.</p> <p>(ii) All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests.</p> <p>(iii) A record of the exposure of each subject to the investigational device, including the date and time of each</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	use, and any other therapy.				
812.140(a)(4)	A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:  The protocol, with documents showing the dates of and reasons for each deviation from the protocol.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.140(a)(5)	A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:  Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.140(b)(1)	A sponsor shall maintain the following accurate, complete, and current records relating to an investigation:  (1) All correspondence with another sponsor, a monitor, an investigator, an IRB, or FDA, including required reports.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.140(b)(2)	A sponsor shall maintain the following accurate, complete, and current records relating to an investigation:  Records of shipment and disposition. Records of shipment shall include the name and address of the consignee, type and quantity of device, date of shipment, and batch number or code mark. Records of disposition shall describe the batch number or code marks of any devices returned to the sponsor, repaired, or disposed of in other ways by the investigator or another person, and the reasons for and method of disposal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.140(b)(3)	A sponsor shall maintain the following accurate, complete, and current records relating to an investigation:  Signed investigator agreements including the financial disclosure information required to be collected under § 812.43(c)(5) in accordance with part 54 of this chapter.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.140(b)(4)(i)	For each investigation subject to § 812.2(b)(1) of a device	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
812.140(b)(4)(ii) 812.140(b)(4)(iii) 812.140(b)(4)(iv) 812.140(b)(4)(v) 812.140(b)(4)(vi)	other than a significant risk device, the records described in paragraph (b)(5) of this section and the following records, consolidated in one location and available for FDA inspection and copying:  (i) The name and intended use of the device and the objectives of the investigation;  (ii) A brief explanation of why the device is not a significant risk device:  (iii) The name and address of each investigator:  (iv) The name and address of each IRB that has reviewed the investigation:  (v) A statement of the extent to which the good manufacturing practice regulation in part 820 will be followed in manufacturing the device; and  (vi) Any other information required by FDA.				
812.140(b)(5) 812.140(b)(6)	A sponsor shall maintain the following accurate, complete, and current records relating to an investigation:  Records concerning adverse device effects (whether anticipated or unanticipated) and complaints and  Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigation or a particular investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.140(c)	An IRB shall maintain records in accordance with part 56 of this chapter.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.140(d)	An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Reg#	Requirement	Yes	N/A	Requires Action	Notes
	development protocol.				
812.140(e)	An investigator or sponsor may withdraw from the responsibility to maintain records for the period required in paragraph (d) of this section and transfer custody of the records to any other person who will accept responsibility for them under this part, including the requirements of § 812.145. Notice of a transfer shall be given to FDA not later than 10 working days after transfer occurs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.145(a)	Entry and inspection. A sponsor or an investigator who has authority to grant access shall permit authorized FDA employees, at reasonable times and in a reasonable manner, to enter and inspect any establishment where devices are held (including any establishment where devices are manufactured, processed, packed, installed, used, or implanted or where records of results from use of devices are kept).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.45(b)	Records inspection. A sponsor, IRB, or investigator, or any other person acting on behalf of such a person with respect to an investigation, shall permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.145(c)	Records identifying subjects. An investigator shall permit authorized FDA employees to inspect and copy records that identify subjects, upon notice that FDA has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or IRB have not been submitted or are incomplete, inaccurate, false, or misleading.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(a)(1)	An investigator shall submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(a)(2)	Withdrawal of IRB approval. An investigator shall report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Reg#	Requirement	Yes	N/A	Requires Action	Notes
812.150(a)(3)	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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(a)(4)	Deviations from the investigational plan. An investigator shall notify the sponsor and the reviewing IRB (see § 56.108(a) (3) and (4)) of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such notice shall be given as soon as possible, but in no event later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, FDA and IRB in accordance with § 812.35(a) also is required.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(a)(5)	Informed consent. If an investigator uses a device without obtaining informed consent, the investigator shall report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(a)(6)	An investigator shall, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(a)(7)	An investigator shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(b)(1)	A sponsor who conducts an evaluation of an unanticipated adverse device effect under § 812.46(b) shall report the results of such evaluation to FDA and to all reviewing IRB's and participating investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter the sponsor shall submit such additional reports concerning the effect as FDA requests.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(b)(2)	A sponsor shall notify FDA and all reviewing IRB's and participating investigators of any withdrawal of approval of an investigation or a part of an investigation by a reviewing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Reg#	Requirement	Yes	N/A	Requires Action	Notes
	IRB within 5 working days after receipt of the withdrawal of approval.				
812.150(b)(3)	A sponsor shall notify all reviewing IRB's and participating investigators of any withdrawal of FDA approval of the investigation, and shall do so within 5 working days after receipt of notice of the withdrawal of approval.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(b)(4)	Current investigator list. A sponsor shall submit to FDA, at 6-month intervals, a current list of the names and addresses of all investigators participating in the investigation. The sponsor shall submit the first such list 6 months after FDA approval.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(b)(5)	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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(b)(6)	A sponsor shall notify FDA and all reviewing IRB's of any request that an investigator return, repair, or otherwise dispose of any units of a device. Such notice shall occur within 30 working days after the request is made and shall state why the request was made.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(b)(7)	In the case of a significant risk device, the sponsor shall notify FDA within 30 working days of the completion or termination of the investigation and shall submit a final report to FDA and all reviewing the IRB's and participating investigators within 6 months after completion or termination. In the case of a device that is not a significant risk device, the sponsor shall submit a final report to all reviewing IRB's within 6 months after termination or completion.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(b)(8)	A sponsor shall submit to FDA a copy of any report by an investigator under paragraph (a)(5) of this section of use of a device without obtaining informed consent, within 5 working days of receipt of notice of such use.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
812.150(b)(9)	If an IRB determines that a device is a significant risk	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	device, and the sponsor had proposed that the IRB consider the device not to be a significant risk device, the sponsor shall submit to FDA a report of the IRB's determination within 5 working days after the sponsor first learns of the IRB's determination.				
812.150(b)(10)	A sponsor shall, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Part 50 Protection of Human Subjects</b>					
50.20	Except as provided in §§ 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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(a)(1)	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:  The human subject is confronted by a life-threatening situation necessitating the use of the test article.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(a)(2)	The obtaining of informed consent shall be deemed feasible	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	<p>unless, before use of the test article (except as provided in paragraph (b) of this section), both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:</p> <p>Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.</p>				
50.23(a)(3)	<p>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:</p> <p>Time is not sufficient to obtain consent from the subject's legal representative.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(a)(4)	<p>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:</p> <p>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.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(b)	<p>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.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.239(c)	<p>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.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)	<p>(d)(1) Under 10 U.S.C. 1107(f) the President may waive the</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	<p>prior consent requirement for the administration of an investigational new drug to a member of the armed forces in connection with the member's participation in a particular military operation. The statute specifies that only the President may waive informed consent in this connection and the President may grant such a waiver only if the President determines in writing that obtaining consent: Is not feasible; is contrary to the best interests of the military member; or is not in the interests of national security. The statute further provides that in making a determination to waive prior informed consent on the ground that it is not feasible or the ground that it is contrary to the best interests of the military members involved, the President shall apply the standards and criteria that are set forth in the relevant FDA regulations for a waiver of the prior informed consent requirements of section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)). Before such a determination may be made that obtaining informed consent from military personnel prior to the use of an investigational drug (including an antibiotic or biological product) in a specific protocol under an investigational new drug application (IND) sponsored by the Department of Defense (DOD) and limited to specific military personnel involved in a particular military operation is not feasible or is contrary to the best interests of the military members involved the Secretary of Defense must first request such a determination from the President, and certify and document to the President that the following standards and criteria contained in paragraphs (d)(1) through (d)(4) of this section have been met.</p>				
50.23(d)(1)(i)	<p>The extent and strength of evidence of the safety and effectiveness of the investigational new drug in relation to the medical risk that could be encountered during the military operation supports the drug's administration under an IND.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(ii)	<p>The military operation presents a substantial risk that military personnel may be subject to a chemical, biological, nuclear, or other exposure likely to produce death or serious or life-threatening injury or illness.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
50.23(d)(1)(iii)	There is no available satisfactory alternative therapeutic or preventive treatment in relation to the intended use of the investigational new drug.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(iv)	Conditioning use of the investigational new drug on the voluntary participation of each member could significantly risk the safety and health of any individual member who would decline its use, the safety of other military personnel, and the accomplishment of the military mission.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(v)	(v) A duly constituted institutional review board (IRB) established and operated in accordance with the requirements of paragraphs (d)(2) and (d)(3) of this section, responsible for review of the study, has reviewed and approved the investigational new drug protocol and the administration of the investigational new drug without informed consent. DOD's request is to include the documentation required by § 56.115(a)(2) of this chapter.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(vi)(A)	DOD has explained:  The context in which the investigational drug will be administered, e.g., the setting or whether it will be self-administered or it will be administered by a health professional;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(vi)(B)	DOD has explained:  The nature of the disease or condition for which the preventive or therapeutic treatment is intended; and	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(vi)(C)	DOD has explained:  To the extent there are existing data or information available, information on conditions that could alter the effects of the investigational drug.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(vii)	DOD's recordkeeping system is capable of tracking and will be used to track the proposed treatment from supplier to the individual recipient.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(viii)	Each member involved in the military operation will be given, prior to the administration of the investigational new drug, a specific written information sheet (including	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	information required by 10 U.S.C. 1107(d) concerning the investigational new drug, the risks and benefits of its use, potential side effects, and other pertinent information about the appropriate use of the product.				
50.23(d)(1)(i)(ix)	Medical records of members involved in the military operation will accurately document the receipt by members of the notification required by paragraph (d)(1)(viii) of this section.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(x)	Medical records of members involved in the military operation will accurately document the receipt by members of any investigational new drugs in accordance with FDA regulations including part 312 of this chapter.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(xi)	DOD will provide adequate followup to assess whether there are beneficial or adverse health consequences that result from the use of the investigational product.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(xii)	DOD is pursuing drug development, including a time line, and marketing approval with due diligence.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(xiii)	FDA has concluded that the investigational new drug protocol may proceed subject to a decision by the President on the informed consent waiver request.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(xiv)	DOD will provide training to the appropriate medical personnel and potential recipients on the specific investigational new drug to be administered prior to its use.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(xv)	DOD has stated and justified the time period for which the waiver is needed, not to exceed one year, unless separately renewed under these standards and criteria.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(xvi)	DOD shall have a continuing obligation to report to the FDA and to the President any changed circumstances relating to these standards and criteria (including the time period referred to in paragraph (d)(1)(xv) of this section) or that otherwise might affect the determination to use an investigational new drug without informed consent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(1)(i)(xvii)	DOD is to provide public notice as soon as practicable and consistent with classification requirements through notice in the Federal Register describing each waiver of informed consent determination, a summary of the most updated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	scientific information on the products used, and other pertinent information.				
50.23(d)(1)(i)(xviii)	Use of the investigational drug without informed consent otherwise conforms with applicable law.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(2)	The duly constituted institutional review board, described in paragraph (d)(1)(v) of this section, must include at least 3 nonaffiliated members who shall not be employees or officers of the Federal Government (other than for purposes of membership on the IRB) and shall be required to obtain any necessary security clearances. This IRB shall review the proposed IND protocol at a convened meeting at which a majority of the members are present including at least one member whose primary concerns are in nonscientific areas and, if feasible, including a majority of the nonaffiliated members. The information required by § 56.115(a)(2) of this chapter is to be provided to the secretary of Defense for further review.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(3)(i)	The duly constituted institutional review board, described in paragraph (d)(1)(v) of this section, must review and approve:  The required information sheet;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(3)(ii)	The duly constituted institutional review board, described in paragraph (d)(1)(v) of this section, must review and approve:  The adequacy of the plan to disseminate information, including distribution of the information sheet to potential recipients, on the investigational product (e.g., in forms other than written);	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(3)(iii)	The duly constituted institutional review board, described in paragraph (d)(1)(v) of this section, must review and approve:  The adequacy of the information and plans for its dissemination to health care providers, including potential side effects, contraindications, potential interactions, and other pertinent considerations; and	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
50.23(d)(3)(iv)	The duly constituted institutional review board, described in paragraph (d)(1)(v) of this section, must review and approve:  An informed consent form as required by part 50 of this chapter, in those circumstances in which DOD determines that informed consent may be obtained from some or all personnel involved.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(4)	DOD is to submit to FDA summaries of institutional review board meetings at which the proposed protocol has been reviewed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.23(d)(5)	Nothing in these criteria or standards is intended to preempt or limit FDA's and DOD's authority or obligations under applicable statutes and regulations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(a)(1)	The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve that investigation without requiring that informed consent of all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following:  The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(a)(2)(i)	Obtaining informed consent is not feasible because:  The subjects will not be able to give their informed consent as a result of their medical condition;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(a)(2)(ii)	Obtaining informed consent is not feasible because:  The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
50.24(a)(2)(iii)	<p>Obtaining informed consent is not feasible because:</p> <p>There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(a)(3)(i)	<p>The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve that investigation without requiring that informed consent of all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following:</p> <p>Subjects are facing a life-threatening situation that necessitates intervention;</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(a)(3)(ii)	<p>The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve that investigation without requiring that informed consent of all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following:</p> <p>Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(a)(3)(iii)	<p>The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve that investigation without requiring that informed consent of all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following:</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.				
50.24(a)(4)	The clinical investigation could not practicably be carried out without the waiver.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(a)(5)	The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(a)(6)	The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with § 50.25. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation consistent with paragraph (a)(7)(v) of this section.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(a)(7)(i)	Additional protections of the rights and welfare of the subjects will be provided, including, at least:  Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(a)(7)(ii)	Additional protections of the rights and welfare of the subjects will be provided, including, at least:  Public disclosure to the communities in which the clinical	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits;				
50.24(a)(7)(iii)	<p>Additional protections of the rights and welfare of the subjects will be provided, including, at least:</p> <p>Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(a)(7)(iv)	<p>Additional protections of the rights and welfare of the subjects will be provided, including, at least:</p> <p>Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation; and</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(a)(7)(v)	<p>Additional protections of the rights and welfare of the subjects will be provided, including, at least:</p> <p>If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(b)	The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	<p>The IRB shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible.</p>				
50.24(c)	<p>The IRB determinations required by paragraph (a) of this section and the documentation required by paragraph (e) of this section are to be retained by the IRB for at least 3 years after completion of the clinical investigation, and the records shall be accessible for inspection and copying by FDA in accordance with § 56.115(b) of this chapter.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(d)	<p>Protocols involving an exception to the informed consent requirement under this section must be performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies such protocols as protocols that may include subjects who are unable to consent. The submission of those protocols in a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists. Applications for investigations under this section may not be submitted as amendments under §§ 312.30 or 812.35 of this chapter.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.24(e)	<p>If an IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in the exception provided under paragraph (a) of this section or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the clinical investigator and to</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	the sponsor of the clinical investigation. The sponsor of the clinical investigation must promptly disclose this information to FDA and to the sponsor's clinical investigators who are participating or are asked to participate in this or a substantially equivalent clinical investigation of the sponsor, and to other IRB's that have been, or are, asked to review this or a substantially equivalent investigation by that sponsor.				
50.25(a)(1)	Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:  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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.25(a)(2)	Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:  A description of any reasonably foreseeable risks or discomforts to the subject.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.25(a)(3)	Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:  A description of any benefits to the subject or to others which may reasonably be expected from the research.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.25(a)(4)	Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:  A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.25(a)(5)	Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	<p>subject:</p> <p>A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.</p>				
50.25(a)(6)	<p>Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:</p> <p>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.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.25(a)(7)	<p>Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:</p> <p>An explanation of whom to contact for answers to pertinent questions about the research and research subjects` rights, and whom to contact in the event of a research-related injury to the subject.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.25(a)(8)	<p>Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:</p> <p>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.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.25(b)(1)	<p>Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:</p> <p>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</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	unforeseeable.				
50.25(b)(2)	Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:  Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.25(b)(3)	Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:  Any additional costs to the subject that may result from participation in the research.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.25(b)(4)	Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:  The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.25(b)(5)	Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:  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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.25(b)(6)	Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:  The approximate number of subjects involved in the study.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form.				
50.27(b)(1)	<p>Except as provided in § 56.109(c), the consent form may be either of the following:</p> <p>A written consent document that embodies the elements of informed consent required by § 50.25. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.27(b)(2)	<p>Except as provided in § 56.109(c), the consent form may be either of the following:</p> <p>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.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.50	In addition to other responsibilities assigned to IRBs under this part and part 56 of this chapter, each IRB must review clinical investigations involving children as subjects covered by this subpart D and approve only those clinical investigations that satisfy the criteria described in § 50.51, § 50.52, or § 50.53 and the conditions of all other applicable sections of this subpart D.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.51	Any clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter in which no greater than minimal risk to children is presented may involve children as subjects only if the IRB finds and documents that	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians as set forth in § 50.55.				
50.52(a)	Any clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter in which more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, may involve children as subjects only if the IRB finds and documents that:  The risk is justified by the anticipated benefit to the subjects;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.52(b)	The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.52(c)	Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians as set forth in § 50.55.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.53(a)	Any clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter in which more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well-being of the subject, may involve children as subjects only if the IRB finds and documents that:  The risk represents a minor increase over minimal risk;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.53(b)	Any clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter in which more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well-being of the subject, may involve children as subjects only if the IRB finds and documents that:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;				
50.53(c)	<p>Any clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter in which more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well-being of the subject, may involve children as subjects only if the IRB finds and documents that:</p> <p>The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.53(d)	<p>Any clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter in which more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well-being of the subject, may involve children as subjects only if the IRB finds and documents that:</p> <p>Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians as set forth in § 50.55.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.54(a)	<p>If an IRB does not believe that a clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter and involving children as subjects meets the requirements of § 50.51, § 50.52, or § 50.53, the clinical investigation may proceed only if:</p> <p>The IRB finds and documents that the clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
50.54(b)(1)	The Commissioner of Food and Drugs, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, determines either:  That the clinical investigation in fact satisfies the conditions of § 50.51, § 50.52, or § 50.53, as applicable, or	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.54(b)(2)(i)	That the following conditions are met:  The clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.54(b)(2)(ii)	That the following conditions are met:  The clinical investigation will be conducted in accordance with sound ethical principles; and	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.54(b)(2)(iii)	That the following conditions are met:  Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians as set forth in § 50.55.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.55(a)	The IRB must determine that adequate provisions are made for soliciting the assent of the children when in the judgment of the IRB the children are capable of providing assent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.55(b)	In determining whether children are capable of providing assent, the IRB must take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in clinical investigations under a particular protocol, or for each child, as the IRB deems appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.55(c)(1)	The assent of the children is not a necessary condition for proceeding with the clinical investigation if the IRB determines:  That the capability of some or all of the children is so limited	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	that they cannot reasonably be consulted, or				
50.55(c)(2)	That the intervention or procedure involved in the clinical investigation holds out a prospect of direct benefit that is important to the health or well- being of the children and is available only in the context of the clinical investigation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.55(d)(1)	Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement if it finds and documents that:  The clinical investigation involves no more than minimal risk to the subjects;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.55(d)(2)	Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement if it finds and documents that:  The waiver will not adversely affect the rights and welfare of the subjects;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.55(d)(3)	Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement if it finds and documents that:  The clinical investigation could not practicably be carried out without the waiver; and	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.55(d)(4)	Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement if it finds and documents that:  Whenever appropriate, the subjects will be provided with additional pertinent information after participation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.55(e)	In addition to the determinations required under other applicable sections of this subpart D, the IRB must determine that the permission of each child's parents or guardian is granted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.55(e)(1)	Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient, if consistent with State law, for clinical investigations to be conducted under § 50.51 or § 50.52.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Reg#	Requirement	Yes	N/A	Requires Action	Notes
50.55(e)(2)	Where clinical investigations are covered by § 50.53 or § 50.54 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child if consistent with State law.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.55(f)	Permission by parents or guardians must be documented in accordance with and to the extent required by § 50.27.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.55(g)	When the IRB determines that assent is required, it must also determine whether and how assent must be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.56(a)(1)	Children who are wards of the State or any other agency, institution, or entity can be included in clinical investigations approved under § 50.53 or § 50.54 only if such clinical investigations are:  Related to their status as wards; or	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.56(a)(2)	Children who are wards of the State or any other agency, institution, or entity can be included in clinical investigations approved under § 50.53 or § 50.54 only if such clinical investigations are:  Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.56(b)	If the clinical investigation is approved under paragraph (a) of this section, the IRB must require appointment of an advocate for each child who is a ward.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.56(b)(1)	The advocate will serve in addition to any other individual acting on behalf of the child as guardian or in loco parentis.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.56(b)(2)	One individual may serve as advocate for more than one child.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
50.56(b)(3)	The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	participation in the clinical investigation.				
50.56(b)(4)	The advocate must not be associated in any way (except in the role as advocate or member of the IRB) with the clinical investigation, the investigator(s), or the guardian organization.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Part 56 Institutional Review Boards</b>					
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 Food and Drug Administration 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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.103(b)	Except as provided in §§ 56.104 and 56.105, the Food and Drug Administration 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 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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.104(a)	The following categories of clinical investigations are exempt from the requirements of this part for IRB review:  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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.104(b)	The following categories of clinical investigations are exempt from the requirements of this part for IRB review:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	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.				
56.104(c)	<p>The following categories of clinical investigations are exempt from the requirements of this part for IRB review:</p> <p>Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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 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 or 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	experienced in working with those subjects.				
56.107(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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.107(c)	Each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.107(d)	Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.107(e)	No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.107(f)	An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB. No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.108(a)	In order to fulfill the requirements of these regulations, each IRB shall:  Follow written procedures: (1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (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; (3) for ensuring prompt reporting to the IRB of changes in research activity; and (4)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	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.				
56.108(b)	<p>In order to fulfill the requirements of these regulations, each IRB shall:</p> <p>Follow written procedures: (1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (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; (3) for ensuring prompt reporting to the IRB of changes in research activity; and (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.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.108(c)	<p>In order to fulfill the requirements of these regulations, each IRB shall:</p> <p>Except when an expedited review procedure is used (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 for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.109(b)	An IRB shall require that information given to subjects as part of informed consent is in accordance with § 50.25. The IRB may require that information, in addition to that specifically mentioned in § 50.25, be given to the subjects when in the IRB's judgment the information would	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	meaningfully add to the protection of the rights and welfare of subjects.				
56.109(c)(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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.109(c)(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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.109(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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.109(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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Reg#	Requirement	Yes	N/A	Requires Action	Notes
56.109(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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.109(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 is 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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.110(b)	An IRB may use the expedited review procedure to review either or both of the following: (1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk, (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).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.110(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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.110(d)	The Food and Drug Administration may restrict, suspend, or terminate an institution's or Rib's use of the expedited review procedure when necessary to protect the rights or	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	welfare of subjects.				
56.111(a)(1)	<p>In order to approve research covered by these regulations the IRB shall determine that the following requirements are satisfied:</p> <p>Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and 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.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.111(a)(2)	<p>In order to approve research covered by these regulations the IRB shall determine that the following requirements are satisfied:</p> <p>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 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.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.111(a)(3)	<p>In order to approve research covered by these regulations the IRB shall determine that the following requirements are satisfied:</p> <p>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.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
56.111(a)(4)	In order to approve research covered by these regulations the IRB shall determine that the following requirements are satisfied:  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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.111(a)(5)	In order to approve research covered by these regulations the IRB shall determine that the following requirements are satisfied:  Informed consent will be appropriately documented, in accordance with and to the extent required by § 50.27.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.111(a)(6)	In order to approve research covered by these regulations the IRB shall determine that the following requirements are satisfied:  Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.111(a)(7)	In order to approve research covered by these regulations the IRB shall determine that the following requirements are satisfied:  Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.111(b)	In order to approve research covered by these regulations the IRB shall determine that the following requirements are satisfied:  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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
56.111(c)	In order to approve research covered by these regulations the IRB shall determine that the following requirements are satisfied:  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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.115(a)(1)	An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:  Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.115(a)(2)	An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including minutes of IRB meetings 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	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.				
56.115(a)(3)	An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including records of continuing review activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.115(a)(4)	An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including copies of all correspondence between the IRB and the investigators.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.115(a)(5)	An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including 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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.115(a)(6)	An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including written procedures for the IRB as required by § 56.108 (a) and (b).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.115(a)(7)	An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including statements of significant new findings provided to subjects, as required by § 50.25.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.115(b)	An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	reasonable manner.				
56.115(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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.120(a)	If apparent noncompliance with these regulations in the operation of an IRB is observed by an FDA investigator during an inspection, the inspector will present an oral or written summary of observations to an appropriate representative of the IRB. The Food and Drug Administration may subsequently send a letter describing the noncompliance to the IRB and to the parent institution. The agency will require that the IRB or the parent institution respond to this letter within a time period specified by FDA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.120(b)(1)	On the basis of the IRB's or the institution's response, FDA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, the agency may:  Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.120(b)(2)	On the basis of the IRB's or the institution's response, FDA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, the agency may:  Direct that no new subjects be added to ongoing studies subject to this part;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.120(b)(3)	On the basis of the IRB's or the institution's response, FDA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	<p>institution takes appropriate corrective action, the agency may:</p> <p>Terminate ongoing studies subject to this part when doing so would not endanger the subjects; or</p>				
56.120(b)(4)	When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, the agency may notify relevant State and Federal regulatory agencies and other parties with a direct interest in the agency's action of the deficiencies in the operation of the IRB.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.120(c)	The parent institution is presumed to be responsible for the operation of an IRB, and the Food and Drug Administration will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, the Food and Drug Administration may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.121(b)(1)	<p>The Commissioner may disqualify an IRB or the parent institution if the Commissioner determines that:</p> <p>The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.121(b)(2)	<p>The Commissioner may disqualify an IRB or the parent institution if the Commissioner determines that:</p> <p>The noncompliance adversely affects the rights or welfare of the human subjects in a clinical investigation.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.121(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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	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.				
56.121(d)	The Food and Drug Administration will not approve an application for a research permit for a clinical investigation that is to be under the review of a disqualified IRB or that is to be conducted at a disqualified institution, and it may refuse to consider in support of a marketing permit the data from a clinical investigation that was reviewed by a disqualified IRB as conducted at a disqualified institution, unless the IRB or the parent institution is reinstated as provided in § 56.123.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.122	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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.123	An IRB or an institution may be reinstated if the Commissioner determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under § 56.121(c).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
56.124	Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, through the Department of Justice institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. The agency may also refer pertinent matters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Part 54</b> <b>Financial Disclosure by Clinical Investigators</b>					



Reg#	Requirement	Yes	N/A	Requires Action	Notes
54.3	The applicant is responsible for making the appropriate certification or disclosure statement where the applicant either contracted with one or more clinical investigators to conduct the studies or submitted studies conducted by others not under contract to the applicant.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.4(a)	The applicant (of an application submitted under sections 505, 506, 510(k), 513, or 515 of the Federal Food, Drug, and Cosmetic Act, or section 351 of the Public Health Service Act) that relies in whole or in part on clinical studies shall submit, for each clinical investigator who participated in a covered clinical study, either a certification described in paragraph (a)(1) of this section or a disclosure statement described in paragraph (a)(3) of this section.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.4(a)(1)	Certification: The applicant covered by this section shall submit for all clinical investigators (as defined in § 54.2(d)), to whom the certification applies, a completed Form FDA 3454 attesting to the absence of financial interests and arrangements described in paragraph (a)(3) of this section. The form shall be dated and signed by the chief financial officer or other responsible corporate official or representative.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.4(a)(2)	If the certification covers less than all covered clinical data in the application, the applicant shall include in the certification a list of the studies covered by this certification.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.4(a)(3)(i)	Disclosure Statement: For any clinical investigator defined in § 54.2(d) for whom the applicant does not submit the certification described in paragraph (a)(1) of this section, the applicant shall submit a completed Form FDA 3455 disclosing completely and accurately the following:  Any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of a covered clinical trial, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.4(a)(3)(ii)	Disclosure Statement: For any clinical investigator defined in § 54.2(d) for whom the applicant does not submit the	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	<p>certification described in paragraph (a)(1) of this section, the applicant shall submit a completed Form FDA 3455 disclosing completely and accurately the following:</p> <p>Any significant payments of other sorts from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;</p>				
54.4(a)(3)(iii)	<p>Disclosure Statement: For any clinical investigator defined in § 54.2(d) for whom the applicant does not submit the certification described in paragraph (a)(1) of this section, the applicant shall submit a completed Form FDA 3455 disclosing completely and accurately the following:</p> <p>Any proprietary interest in the tested product held by any clinical investigator involved in a study;</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.4(a)(3)(iv)	<p>Disclosure Statement: For any clinical investigator defined in § 54.2(d) for whom the applicant does not submit the certification described in paragraph (a)(1) of this section, the applicant shall submit a completed Form FDA 3455 disclosing completely and accurately the following:</p> <p>Any significant equity interest in the sponsor of the covered study held by any clinical investigator involved in any clinical study; and</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.4.(a)(3)(v)	<p>Disclosure Statement: For any clinical investigator defined in § 54.2(d) for whom the applicant does not submit the certification described in paragraph (a)(1) of this section, the applicant shall submit a completed Form FDA 3455 disclosing completely and accurately the following:</p> <p>Any steps taken to minimize the potential for bias resulting from any of the disclosed arrangements, interests, or payments.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.4(b)	<p>The clinical investigator shall provide to the sponsor of the covered study sufficient accurate financial information to allow the sponsor to submit complete and accurate certification or disclosure statements as required in paragraph (a) of this section. The investigator shall</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	promptly update this information if any relevant changes occur in the course of the investigation or for 1 year following completion of the study.				
54.4.(c)	Refusal to file application. FDA may refuse to file any marketing application described in paragraph (a) of this section that does not contain the information required by this section or a certification by the applicant that the applicant has acted with due diligence to obtain the information but was unable to do so and stating the reason.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.5(a)	Evaluation of disclosure statement. FDA will evaluate the information disclosed under § 54.4(a)(2) about each covered clinical study in an application to determine the impact of any disclosed financial interests on the reliability of the study. FDA may consider both the size and nature of a disclosed financial interest (including the potential increase in the value of the interest if the product is approved) and steps that have been taken to minimize the potential for bias.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.5(b)	Effect of study design. In assessing the potential of an investigator's financial interests to bias a study, FDA will take into account the design and purpose of the study. Study designs that utilize such approaches as multiple investigators (most of whom do not have a disclosable interest), blinding, objective endpoints, or measurement of endpoints by someone other than the investigator may adequately protect against any bias created by a disclosable financial interest.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.5(c)(1) 54.5(c)(2) 54.5(c)(3) 54.5(c)(4)	Agency actions to ensure reliability of data. If FDA determines that the financial interests of any clinical investigator raise a serious question about the integrity of the data, FDA will take any action it deems necessary to ensure the reliability of the data including:  (1) Initiating agency audits of the data derived from the clinical investigator in question;  (2) Requesting that the applicant submit further analyses of data, e.g., to evaluate the effect of the clinical investigator's data on overall study outcome;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	<p>(3) Requesting that the applicant conduct additional independent studies to confirm the results of the questioned study; and</p> <p>(4) Refusing to treat the covered clinical study as providing data that can be the basis for an agency action.</p>				
54.6(a)	Financial records of clinical investigators to be retained. An applicant who has submitted a marketing application containing covered clinical studies shall keep on file certain information pertaining to the financial interests of clinical investigators who conducted studies on which the application relies and who are not full or part-time employees of the applicant, as follows:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.6(a)(1)	Complete records showing any financial interest or arrangement as described in § 54.4(a)(3)(i) paid to such clinical investigators by the sponsor of the covered study.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.6(a)(2)	Complete records showing significant payments of other sorts, as described in § 54.4(a)(3)(ii), made by the sponsor of the covered clinical study to the clinical investigator.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.6(a)(3)	Complete records showing any financial interests held by clinical investigators as set forth in § 54.4(a)(3)(iii) and (a)(3)(iv).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
54.6(b)(1) 54.6(b)(2)	<p>Requirements for maintenance of clinical investigators' financial records.</p> <p>(1) For any application submitted for a covered product, an applicant shall retain records as described in paragraph (a) of this section for 2 years after the date of approval of the application.</p> <p>(2) The person maintaining these records shall, upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to and copy and verify these records.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<p><b>Part 820</b> <b>Quality System Regulation</b></p>					



Reg#	Requirement	Yes	N/A	Requires Action	Notes
820.5	Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.20(a)	Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.20(b)(1)	Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.20(b)(2)	Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.20(b)(3)(i) 820.20(b)(3)(ii)	Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:  (i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and  (ii) Reporting on the performance of the quality system to management with executive responsibility for review.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.20(c)	Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
820.20(d)	Each manufacturer shall establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured. The manufacturer shall establish how the requirements for quality will be met.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.20(e)	Each manufacturer shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.22	Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and reaudits shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.25(a)	Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.25(b)	Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.25(b)(1)	As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.25(b)(2)	Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.30(a)(1)	Each manufacturer of any class III or class II device, and	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes												
	the class I devices listed in this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.																
820.30(a)(2)(i) 820.30(a)(2)(ii)	<p>The following class I devices are subject to design controls:</p> <p>(i) Devices automated with computer software; and</p> <p>(ii) The devices listed in the following chart.</p> <table border="1" data-bbox="426 557 1001 784"> <thead> <tr> <th data-bbox="426 557 793 618">Section</th> <th data-bbox="793 557 1001 618">Device</th> </tr> </thead> <tbody> <tr> <td data-bbox="426 618 793 654">868.6810</td> <td data-bbox="793 618 1001 654">Catheter, Tracheobronchial Suction.</td> </tr> <tr> <td data-bbox="426 654 793 690">878.4460</td> <td data-bbox="793 654 1001 690">Glove, Surgeon`s.</td> </tr> <tr> <td data-bbox="426 690 793 725">880.6760</td> <td data-bbox="793 690 1001 725">Restraint, Protective.</td> </tr> <tr> <td data-bbox="426 725 793 761">892.5650</td> <td data-bbox="793 725 1001 761">System, Applicator, Radionuclide, Manual.</td> </tr> <tr> <td data-bbox="426 761 793 797">892.5740</td> <td data-bbox="793 761 1001 797">Source, Radionuclide Teletherapy.</td> </tr> </tbody> </table>	Section	Device	868.6810	Catheter, Tracheobronchial Suction.	878.4460	Glove, Surgeon`s.	880.6760	Restraint, Protective.	892.5650	System, Applicator, Radionuclide, Manual.	892.5740	Source, Radionuclide Teletherapy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Section	Device																
868.6810	Catheter, Tracheobronchial Suction.																
878.4460	Glove, Surgeon`s.																
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892.5650	System, Applicator, Radionuclide, Manual.																
892.5740	Source, Radionuclide Teletherapy.																
820.30(b)	Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>													
820.30(c)	Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>													
820.30(d)	Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>													

Reg#	Requirement	Yes	N/A	Requires Action	Notes
	input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.				
820.30(e)	Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (the DHF).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.30(f)	Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.30(g)	Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.30(h)	Each manufacturer shall establish and maintain procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	to ensure that the device design is correctly translated into production specifications.				
820.30(i)	Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.30(j)	Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.40(a)	Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part. The approval, including the date and signature of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this part shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.40(b)	Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Approved changes shall be communicated to the appropriate personnel in a timely manner. Each manufacturer shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.50(a)(1)	Each manufacturer shall establish and maintain the requirements, including quality requirements that must be met by suppliers, contractors, and consultants. Each manufacturer shall:  (1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	requirements, including quality requirements. The evaluation shall be documented.				
820.50(a)(2)	Each manufacturer shall:  Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.50(a)(3)	Each manufacturer shall:  Establish and maintain records of acceptable suppliers, contractors, and consultants.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.50(b)	Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with § 820.40.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.60	Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mixups.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.65	Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.70(a)(1)	Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	<p>device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:</p> <p>Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;</p>				
820.70(a)(2)	<p>Where process controls are needed they shall include:</p> <p>Monitoring and control of process parameters and component and device characteristics during production;</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.70(a)(3)	<p>Where process controls are needed they shall include:</p> <p>Compliance with specified reference standards or codes;</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.70(a)(4)	<p>Where process controls are needed they shall include:</p> <p>The approval of processes and process equipment;</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.70(a)(5)	<p>Where process controls are needed they shall include:</p> <p>Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.70(b)	<p>Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to § 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with § 820.40.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.70(c)	<p>Where environmental conditions could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures to adequately control these environmental conditions. Environmental control system(s) shall be periodically inspected to verify that the system, including necessary</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	equipment, is adequate and functioning properly. These activities shall be documented and reviewed.				
820.70(d)	Each manufacturer shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and product or environment could reasonably be expected to have an adverse effect on product quality. The manufacturer shall ensure that maintenance and other personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained individual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.70(e)	Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.70(f)	Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mixups, and assure orderly handling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.70(g)	Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.70(g)(1)	Each manufacturer shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.70(g)(2)	Each manufacturer shall conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules. The inspections, including the date and individual(s) conducting the inspections, shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.70(g)(3)	Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted on or	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.				
820.70(h)	Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.70(i)	When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.72(a)	Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.72(b)	Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on the device's quality. These activities shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.72(b)(1)	Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.				
820.72(b)(2)	The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.75(a)	Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.75(b)	Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.75(b)(1)	Each manufacturer shall ensure that validated processes are performed by qualified individual(s).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.75(b)(2)	For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.75(c)	When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.80(a)	Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
820.80(b)	Each manufacturer shall establish and maintain procedures for acceptance of incoming product. Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.80(c)	Each manufacturer shall establish and maintain acceptance procedures, where appropriate, to ensure that specified requirements for in-process product are met. Such procedures shall ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.80(d)(1) 820.80(d)(2) 820.80(d)(3) 820.80(d)(4)	Final acceptance activities. Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until:  (1) The activities required in the DMR are completed;  (2) the associated data and documentation is reviewed;  (3) the release is authorized by the signature of a designated individual(s); and  (4) the authorization is dated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.80(e)	Each manufacturer shall document acceptance activities required by this part. These records shall include:  (1) The acceptance activities performed;  (2) the dates acceptance activities are performed;  (3) the results;  (4) the signature of the individual(s) conducting the acceptance activities; and	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	(5) where appropriate the equipment used. These records shall be part of the DHR.				
820.86	Each manufacturer shall identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. The identification of acceptance status shall be maintained throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.90(a)	Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.90(b)(1)	Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.90(b)(2)	Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.100(a)(1)	Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;				
820.100(a)(2)	The procedures shall include requirements for:  Investigating the cause of nonconformities relating to product, processes, and the quality system;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.100(a)(3)	The procedures shall include requirements for:  Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.100(a)(4)	The procedures shall include requirements for:  Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.100(a)(5)	The procedures shall include requirements for:  Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.100(a)(6)	The procedures shall include requirements for:  Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.100(a)(7)	Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.100(b)	All activities required under this section, and their results,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	shall be documented.				
820.120(a)	Each manufacturer shall establish and maintain procedures to control labeling activities.  Labels shall be printed and applied so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and where appropriate use.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.120(b)	Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct expiration date, control number, storage instructions, handling instructions, and any additional processing instructions. The release, including the date and signature of the individual(s) performing the examination, shall be documented in the DHR.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.120(c)	Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mixups.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.120(d)	Each manufacturer shall control labeling and packaging operations to prevent labeling The label and labeling used for each production unit, lot, or batch shall be documented in the DHR.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.120(e)	Where a control number is required by § 820.65, that control number shall be on or shall accompany the device through distribution.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.130	Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.140	Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.150(a)	Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.				
820.150(b)	Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.160(a)	Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. Where a device's fitness for use or quality deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.160(b)(1) 820.160(b)(2) 820.160(b)(3) 820.160(b)(4)	(b) Each manufacturer shall maintain distribution records which include or refer to the location of:  (1) The name and address of the initial consignee;  (2) The identification and quantity of devices shipped;  (3) The date shipped; and  (4) Any control number(s) used.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.170(a)	Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
820.170(b)	The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the manufacturer's instructions and procedures and shall document the inspection and any test results to demonstrate proper installation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.180	All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.180(a)	Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.180(b)	Record retention period. All records required by this part shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.180(c)	This section does not apply to the reports required by § 820.20(c) Management review, § 820.22 Quality audits, and supplier audit reports used to meet the requirements of § 820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
820.181(a)	<p>Each manufacturer shall maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared and approved in accordance with § 820.40. The DMR for each type of device shall include, or refer to the location of, the following information:</p> <p>Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.181(b)	<p>The DMR for each type of device shall include, or refer to the location of, the following information:</p> <p>Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.181(c)	<p>The DMR for each type of device shall include, or refer to the location of, the following information:</p> <p>Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.181(d)	<p>The DMR for each type of device shall include, or refer to the location of, the following information:</p> <p>Packaging and labeling specifications, including methods and processes used; and</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.181(e)	<p>The DMR for each type of device shall include, or refer to the location of, the following information:</p> <p>Installation, maintenance, and servicing procedures and methods.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.184(a)	<p>Each manufacturer shall maintain device history records (DHR's). Each manufacturer shall establish and maintain procedures to ensure that DHR's for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR and the requirements of this part. The DHR shall include, or refer to the location of, the following information:</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	The dates of manufacture;				
820.184(b)	The DHR shall include, or refer to the location of, the following information:  The quantity manufactured;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.184(c)	The DHR shall include, or refer to the location of, the following information:  The quantity released for distribution;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.184(d)	The DHR shall include, or refer to the location of, the following information:  The acceptance records which demonstrate the device is manufactured in accordance with the DMR;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.184(e)	The DHR shall include, or refer to the location of, the following information:  The primary identification label and labeling used for each production unit; and	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.184(f)	The DHR shall include, or refer to the location of, the following information:  Any device identification(s) and control number(s) used.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.186	Each manufacturer shall maintain a quality system record (QSR). The QSR shall include, or refer to the location of, procedures and the documentation of activities required by this part that are not specific to a particular type of device(s), including, but not limited to, the records required by § 820.20. Each manufacturer shall ensure that the QSR is prepared and approved in accordance with § 820.40.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.198(a)(1) 820.198(a)(2) 820.198(a)(3)	Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
	<p>(1) All complaints are processed in a uniform and timely manner;</p> <p>(2) Oral complaints are documented upon receipt; and</p> <p>(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 or 804 of this chapter, Medical Device Reporting.</p>				
820.198(b)	Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.198(c)	Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.198(d)(1) 820.198(d)(2) 820.198(d)(3)	<p>Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by § 820.198(e), records of investigation under this paragraph shall include a determination of:</p> <p>(1) Whether the device failed to meet specifications;</p> <p>(2) Whether the device was being used for treatment or diagnosis; and</p> <p>(3) The relationship, if any, of the device to the reported incident or adverse event.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.198(e)(1) 820.198(e)(2) 820.198(e)(3)	When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
820.198(e)(4) 820.198(e)(5) 820.198(e)(6) 820.198(e)(7) 820.198(e)(8)	The record of investigation shall include:  (1) The name of the device;  (2) The date the complaint was received;  (3) Any device identification(s) and control number(s) used;  (4) The name, address, and phone number of the complainant;  (5) The nature and details of the complaint;  (6) The dates and results of the investigation;  (7) Any corrective action taken; and  (8) Any reply to the complainant.				
820.198(f)	When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.198(g)(1) 820.198(g)(2)	If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:  (1) A location in the United States where the manufacturer's records are regularly kept; or  (2) The location of the initial distributor.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.200(a)	Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.200(b)	Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with § 820.100.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Reg#	Requirement	Yes	N/A	Requires Action	Notes
820.200(c)	Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 of this chapter shall automatically consider the report a complaint and shall process it in accordance with the requirements of § 820.198.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.200(d)(1) 820.200(d)(2) 820.200(d)(3) 820.200(d)(4) 820.200(d)(5) 820.200(d)(6)	Service reports shall be documented and shall include:  (1) The name of the device serviced;  (2) Any device identification(s) and control number(s) used;  (3) The date of service;  (4) The individual(s) servicing the device;  (5) The service performed; and  (6) The test and inspection data.				
820.250(a)	Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
820.250(b)	Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	