

	Reg. Ref	Yes	No	NA	Comments/Notes
DOES THE INSTITUTION HAVE WRITTEN POLICIES OR PROCEDURES THAT DESCRIBE:					
I The institutional authority under which the IRB is established and empowered.					
II The definition of the purpose of the IRB.					
III The principles governing the IRB to assure that the rights and welfare of human subjects are protected.					
IV The authority of the IRB.					
A. The scope of authority is defined, i.e., what types of studies must be reviewed.					
B. Authority to disapprove, modify or approve studies based upon consideration of human subject protection aspects.	21 CFR 56.109(a)				
C. Authority to require progress reports from the Investigators and oversee the conduct of the study.	21 CFR 56.108(a)(1) & 56.109(f)				
D. Authority to suspend or terminate approval of a study.	21 CFR 56.108(b)(3) & 56.113				
E. Authority to place restrictions on a study.	21 CFR 56.108(a)(1), 109(a) & 113				
V The IRB's Relationship To:					
A. The top administration of the institution.					
B. The other committees and department chairpersons within the institution.					
C. The research Investigators.					
D. Other institutions.					
E. Regulatory agencies.					
VI The membership of the IRB.					
A. Number of members.	21 CFR 56.107(a)				
B. Qualification of members.	21 CFR 56.107(a)				
C. Diversity of members (for example, representation from the community, and minority groups), including representation by:					
--both men and women	21 CFR 56.107(b)				
-- multiple professions	21 CFR 56.107(a)				
-- scientific and non-scientific member(s)	21 CFR 56.107(c)				

	Reg. Ref	Yes	No	NA	Comments/Notes
-- not otherwise affiliated member(s)	21 CFR 56.107(d)				
D. Alternate members (if used).					
VII Management of the IRB.					
A. The Chairperson:					
-- selection and appointment					
-- length of term/service					
-- duties					
-- removal					
B. The IRB members:					
-- selection and appointment					
-- length of term/service and description of staggered rotation or overlapping of terms, if used					
-- duties					
-- attendance requirements					
--removal					
C. Training of IRB Chair and members:					
-- orientation					
-- continuing education					
-- reference materials (IRB library)					
D. Compensation of IRB members.					
E. Liability coverage for IRB members.					
F. Use of consultants.	21 CFR 56.107(f)				
G. Secretarial/administrative support staff (duties).					
H. Resources (for example, meeting area, filing space, reproduction equipment, computers).					

	Reg. Ref	Yes	No	NA	Comments/Notes
I. Conflict of interest policy:					
-- no selection of IRB members by Investigators					
-- prohibition of participation in IRB deliberations and voting by Investigators.	21 CFR 56.107(e)				
VIII. Functions of the IRB.					
A. Conducting initial and continuing review.	21 CFR 56.108(a)(1) and 56.109(a - f)				
B. Reporting, in writing, findings and actions of the IRB to the Investigator and the institution.	21 CFR 56.108(a)(1) and 56.109(e)				
C. Determining which studies require review more often than annually.	21 CFR 56.108(a)(2) and 56.109(f)				
D. Determining which studies need verification from sources other than the Investigators that no material changes have occurred since previous IRB review.	21 CFR 56.108(a)(2)				
E. Ensuring prompt reporting to the IRB of changes in research activities.	21 CFR 56.108(a)(3)				
F. Ensuring that changes in approved research are not initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards.	21 CFR 56.108(a)(4) and 56.115(a)(1)				
G. Ensuring prompt reporting to the IRB, appropriate institutional officials, and the FDA of:					
* - unanticipated problems involving risks to subjects or others	21 CFR 56.108(b)(1) and 56.115(a)(1)				
* - serious or continuing noncompliance with 21 CFR parts 50 and 56 or the requirements of the IRB	21 CFR 56.108(b)(2)				
* - suspension or termination of IRB approval	21 CFR 56.108(b)(3) and 56.113				
H. Determining which device studies pose significant or non-significant risk.					
IX. Operations of the IRB.					
A. Scheduling of meetings.	21 CFR 56.108(a)(1)				
B. Pre-meeting distribution to members, of, for example, place and time of meeting, agenda, and study material to be reviewed.					
C. The review process:					
-- description of the process ensuring that	21 CFR 56.108(a)(1)				
1) all members receive complete study documentation for review; or					
2) one or more "primary reviewers"/"secondary reviewers" receives the complete study documentation for review, reports to IRB and leads discussion; if other members review summary information only, these members must have access to complete study documentation					

	Reg. Ref	Yes	No	NA	Comments/Notes
-- role of any subcommittees of the IRB					
-- emergency use notification and reporting procedures	21 CFR 56.104(c), 56.108(a)(1) & 108(b)(1)				
-- expedited review procedure	21 CFR 56.108(a)(1) & 56.110(a - c)				
-- for approval of studies that are both minimal risk and on the FDA approved list					
-- for approval of modifications to ongoing studies involving no more than minimal risk					
D. Criteria for IRB approval contain all requirements of 21 CFR 56.111.					
E. Voting requirements:	21 CFR 56.108(c) & 56.107(e - f)				
- quorum required to transact business					
- diversity requirements of quorum (for example requiring at least one physician member when reviewing studies of FDA regulated articles)					
- percent needed to approve or disapprove a study					
- full voting rights of all reviewing members					
- no proxy votes (written or telephone)					
- prohibition against conflict-of-interest voting					
F. Further review/approval of IRB actions by others within the institution. (Override of disapprovals is prohibited.)	21 CFR 56.112				
G. Communication from the IRB:					
- to the Investigator for additional information	21 CFR 56.108(a)(1), 56.109(a) & 56.115(a)(4)				
- to the Investigator conveying IRB decision	21 CFR 56.108(a)(1) & 56.109(e)				
- to institution administration conveying IRB decision	21 CFR 56.108(a)(1) & 56.109(e)				
- to Sponsor of research conveying IRB decision					
H. Appeal of IRB decisions:					
- criteria for appeal					
- to whom appeal is addressed					
- how appeal is resolved (Override of IRB disapprovals by external body/official is prohibited.)	21 CFR 56.112				

		Reg. Ref	Yes	No	NA	Comments/Notes
X	IRB Record Requirements.					
	A. IRB membership roster showing qualifications.	21 CFR 56.115(a)(5)				
	B. Written procedures and guidelines.	21 CFR 56.108(a - b) & 56.115(a)(6)				
	C. Minutes of meetings:	21 CFR 56.115(a)(2)				
	- members present (any consultants/ guests/others shown separately)					
	- summary of discussion on debated issues - record of IRB decisions					
	- record of voting (showing votes for, against and abstentions)					
	D. Retention of protocols reviewed and approved consent documents.	21 CFR 56.115(a)(1)				
	E. Communications to and from the IRB.	21 CFR 56.115(a)(4)				
	F. 1) Adverse reactions reports, and	21 CFR 56.108(a) & 56.115(a)(1 & 4)				
	2) documentation that the IRB reviews such reports.					
	H. Records of continuing review.	21 CFR 56.115(a)(3)				
	I. Record retention requirements. (at least 3 years after completion for FDA studies).	21 CFR 56.115(b)				
	J. Budget and accounting records.					
	K. Emergency use reports.	21 CFR 56.115(a)(4) & 56.104(c)				
	L. Statements of significant new findings provided to subjects.	21 CFR 56.115(a)(7)				
XI	Information the Investigator Provides to the IRB.					
	A. Professional qualifications to do the research (including a description of necessary support services and facilities).					
	B. Study protocol which includes/addresses:	21 CFR 56.103(a) & 56.115(a)(1)				
	- title of the study					
	- purpose of the study (including the expected benefits obtained by doing the study)					
	- sponsor of the study					
	- results of previous related research					
	- subject inclusion/exclusion criteria					

	Reg. Ref	Yes	No	NA	Comments/Notes
- justification for use of any special/vulnerable subject populations (for example, the decisionally impaired, children)					
- study design (including as needed, a discussion of the appropriateness of research methods)					
- description of procedures to be performed					
- provisions for managing adverse reactions					
- the circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable populations					
- the procedures for documentation of informed consent, including any procedures for obtaining assent from minors, using witnesses, translators and document storage					
- compensation to subjects for their participation					
- any compensation for injured research subjects					
- provisions for protection of subject's privacy					
- extra costs to subjects for their participation in the study					
- extra costs to third party payers because of subject's participation					
C. Investigator Brochure (when one exists).	21 CFR 56.111 (a)(2), 56.115(a)(1) & 21 CFR 312.55				
D. The case report form (when one exists).					
E. The proposed informed consent document:	21 CFR 56.111(a)(4 - 5) & 56.111(a)(1)				
- containing all requirements of 21 CFR 50.25(a)					
- containing requirements of 21 CFR 50.25(b) that are appropriate to the study					
- meeting all requirements of 21 CFR 50.20					
- translated consent documents, as necessary, considering likely subject population(s)					
F. Requests for changes in study after initiation.	21 CFR 56.108(a)(4) & 56.115(a)(3 - 4)				
G. Reports of unexpected adverse events.	21 CFR 56.108(b)(1), 115(a)(3 - 4), (b)(1) & 56.113				
H. Progress reports.	21 CFR 56.108(a)(1) & 56.115(a)(1, 3, 4)				
I. Final report.					
J. Institutional forms/reports.					

		Reg. Ref	Yes	No	NA	Comments/Notes
XII	Exemptions From Prospective IRB Review					
	A. Notify IRB within 5 working days.	21 CFR 56.104(c) & 56.108(a)(3)				
	B. Emergency use.	21 CFR 56.102(d) & 56.108(a)(3)				
	C. Review protocol and consent when subsequent use is anticipated.	21 CFR 56.104(c) & 56.108(a)(3). The IRB may elect to use a rapid means of approval is preferable				
XIII	Emergency Research Consent Exception	21 CFR 50.24				
	A. The IRB may find that the 50.24 requirements are met.	21 CFR 56.109(c)(2)				
	B. The IRB shall promptly notify in writing the Investigator and the Sponsor when it determines it cannot approve a 50.24 study.	21 CFR 56.109(e) The written statement shall include a statement of the reasons for the IRB's determination				
	C. The IRB shall provide in writing to the Sponsor a copy of the information that has been publicly disclosed under 50.24(a)(7)(ii) and (a)(7)(iii)	21 CFR 56.109(g)				
	D. In order to approve an emergency research consent waiver study, the IRB must find and document:					
	(1) subjects are in a life-threatening situation, available treatments unproven or unsatisfactory and collection of scientific evidence is necessary	21 CFR 50.24(a)(1)				
	(2) Obtaining informed consent is not feasible because:	21 CFR 50.24(a)(2)				
	- medical condition precludes consent	21 CFR 50.24(a)(2)(i)				
	- no time to get consent from legally authorized representative	21 CFR 50.24(a)(2)(ii)				
	- prospective identity of likely subjects not reasonable	21 CFR 50.24(a)(2)(iii)				
	(3) Prospect of direct benefits to study subjects because:	21 CFR 50.24(a)(3)				
	- life-threatening situation that necessitates treatment					
	- data support potential for direct benefit to individual subjects					
	- risk/benefit of both standard and proposed treatments reasonable					
	(4) waiver needed to carry out study					
	(5) plan defines therapeutic window, during which Investigator will seek consent rather than starting without consent; summary of efforts will be given to IRB at time of continuing review					
	(6) IRB reviews and approves consent procedures and document and approves family member objection procedures					

		Reg. Ref	Yes	No	NA	Comments/Notes
	(7) Additional protections, including at least:					
	- consultation with community representatives					
	- public disclosure of plans, risks and expected benefits					
	- public disclosure of study results					
	- assure an independent Data Monitoring Committee established					
	- objection of family member summarized for continuing review					
	(8) Ensure procedures in place to inform at earliest feasible opportunity of subject's inclusion in the study, participation may be discontinued; procedures to inform family the subject was in the study if subject dies					
	(9) Separate IND or IDE required, even for marketed products					
	(10) IRB disapproval must be documented in writing and sent to the clinical Investigator and the Sponsor of the clinical investigation; Sponsor must promptly disclose to FDA, other Investigators and other IRBs.					