

Checklist for Response to March 6, 2000 Gene Therapy Letter

If there are no patients under active treatment, the sponsor must confirm that provide the following information and assurances in order to adequately address comment 6

Response for inactive IND studies			
Sponsor	Yes	No	No info
Statement that ALL studies under this IND are closed to accrual and there are no patients receiving the IND product (preferably by listing each protocol by title and confirming that each is closed)			
Statement that all of the information regarding the clinical monitoring program will be submitted to the IND <u>prior</u> to resumption of drug administration under the IND (i.e., new protocol submitted, study re-activated, re-treatment of previously enrolled subjects)			
Statement that sponsor will conduct “life-long” follow-up for all patients exposed to gene transfer product			

If the answer to any of the above is not provided, contact sponsor requesting this information as a supplemental response.

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IND/amendment:				
Protocol title:				
Component	Description	Response Adequate	Not Addressed	Not Acceptable
6 (a)	Monitors adherence to study eligibility			
6 (b)	Monitors adherence to treatment plan			
6 (c)	Monitors adherence to the protocol specified data collection for safety and efficacy			
6 (d)	Monitors adherence for reporting of adverse events to: IRB with authority, sponsor or to FDA (if sponsor is also the investigator), and NIH/OBA, including adherence to required timeframes			
6 (e)	Monitors adherence to informed consent requirements (including verification that written and other informed consent materials have been approved by IRB; are signed prior to entry into study; and appropriate witnesses documented)			
6 (f)	Verifies that any modification to the study plan has been submitted to FDA and the IRB with authority prior to implementation and that the IRB has approved the changes			
6 (g)	Audits study reports by verification of the accuracy of the information submitted to FDA, IRB, and NIH by comparison against the primary source documents; maintains a complete set of source documents.			
6 (h)	Procedures are established for mechanism of correction of errors in the study reports and records which includes date of correction, individual making correction, and reason. The mechanism preserves original record.			
6 (i)	Procedures identify individuals responsible for performing monitoring and completion of study report forms & also identifies individual(s) with authority for final verification (sign-off) of study records (usually the PI).			
6 (j)	Procedures are established for receipt and tracking of investigational drug product and individual responsible for tracking drug product is identified.			

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IND/amendment				
Protocol title				
Component	Description	Adequate	Not Addressed	Not Acceptable
6 (k)	Procedures for closing study sites/removing investigators for failure to adhere to protocol			
6 (l)	Organizational chart identifies the individual(s) and/or organization with responsibility for monitoring the clinical study or clinical program			
6 (m)	Organizational chart summarizes the duties of each individual who has monitoring/oversight responsibilities			
6 (n)	Organizational chart provides the reporting relationship between the study monitor/monitoring organization and the IND sponsor			
6 (o)	Organizational chart and summary of responsibilities indicate that the sponsor has adequate oversight			

Check one	Monitoring organization	Comments
	CRO	
	Commercial sponsor-employee(s) perform monitoring	
	Clinical site employee(s) perform monitoring ¹	
	Other (specify in comments)	

¹ specify whether monitor is a “direct report” to the PI or sponsor

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Formal educational training	
Health-related Professional Degree	# monitors with this degree
CRA	
M.D.	
P.A.	
R.N./B.S.N	
Pharm.D./R.Ph.	
Ph.D.	
Other type of degree (specify)	
No information on Profess. Degree	

Other training/certification for clinical monitors	
Clinical monitors certified or accredited	Check one
<ul style="list-style-type: none"> • Yes (one or more) 	
<ul style="list-style-type: none"> • No 	
<ul style="list-style-type: none"> • No information provided 	
Certification or accreditation program	specify name and date of accreditation for each

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Extent of monitoring/auditing program	
Proportion of study records routinely reviewed during study (monitoring)	
Proportion of study records routinely reviewed after study (audit)	
If <100% reviewed, how are records selected for review (check)	
<ul style="list-style-type: none"> • Random 	
<ul style="list-style-type: none"> • Sequential (e.g., every third subject) 	
<ul style="list-style-type: none"> • Other (specify; e.g., patients with AEs) 	
Types of records used to verify CRFS, data	Yes/No
<ul style="list-style-type: none"> • On-site patient charts 	
<ul style="list-style-type: none"> • Outside laboratory reports 	
<ul style="list-style-type: none"> • Outside notes (M.D. notes, letters) 	
<ul style="list-style-type: none"> • Telephone or written follow-up to patients/families 	

Comments:

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Modifications to clinical monitoring program	
Recent changes to monitor program	Check one
<ul style="list-style-type: none">• Yes	
<ul style="list-style-type: none">• No	
<ul style="list-style-type: none">• No information	
If modified in response to 3-6-00 letter or recent RAC mtgs, comment on modifications	Comments:

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Component	Description	Yes	Not addressed	Information exists but not submitted
7 (a)	Confirms that all safety information has been submitted as described in 21 CFR 312.32-33 or			
7 (b)	Has included all information not previously submitted			
7 (b)	Has included all required information but has not submitted all studies (omitted those which sponsor deems are “not required”)			

Comments: