List of documents required for IRB/IEC approval from DGDA

Requirements for the IRB/IEC					
SI. No.	**Types of Documents**	**Availability of Documents**			**Remarks/ Attachment**
		Yes	**No**	**N/A**	
1.	Name of Institution				
2.	Memorandum of article/constitution of IRB/IEC				
3.	Organogram of IRB/IEC				
4.	Focal person's Name, Designation and Contact Information.				
5.	Composition of the IRB/IEC				
6.	TOR (Terms of Reference) of IRB/IEC				
7.	CV of each member of IRB/IEC				
8.	Signed declaration of interests (DOI) of IRB/IEC members.				
9.	The system in place to identify the conflict of interest/ manage the conflict of interest.				
10.	QMS system of IRB/IEC.				
11.	Confirmation of an adequate documentation system in place.				
12.	**Financial transparency of the IRB/IEC** Is there any imposition of a service charge for ethical clearance, and is it publicly available?				
13.	Do they have yearly audit declaration?				
14.	**Voting/opinion system of IRB/IEC:** a. if any member has any conflict of interest with any study that they will review.				
15.	Archiving system and documentation system in place.				
16.	Meeting minutes of IRB/IEC meeting are available.				
17.	Do they follow the Helsinki Declaration while evaluating ethical issues of clinical trial protocol?				
18.	IRB/IEC has access to adequate facilities/ adequate number of competent staff.				
19.	Do they have a system in place for GCP-compliant audit of an approved protocol?				

I, the Chairperson, confirm that our IRB/IEC ……. has the above documents in place. Furthermore, our IRB/IEC has a Quality Management System (QMS) and follows the Helsinki Declaration to manage conflicts of interest. I also confirm that the service charges are available. Additionally, our IRB/IEC possesses adequate facilities and staff.

Stamp
Signature