

IRB Evaluation Report For Authorization

Name of the Institution / Hospital			
<i>University Hospital</i>			
		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Application Type		<input type="checkbox"/> IRB Authorization	<input type="checkbox"/> Affiliation with another authorized IRB
		<input type="checkbox"/> Notification for amendments on existing IRB	
Previous IRB Authorization			
<i>Date</i>			
Is the IRB affiliated to any other Institution		<input type="checkbox"/> Yes	<input type="checkbox"/> No
		<i>Provide details</i>	
MOPH Reference #			
MOPH Submission Date			
Documents Submitted			
#	Document	Checked (Yes √ / No ×)	Page # of the file submitted
1	The IRB role, objective & purpose & Mission statement of the Hospital		
2	Working procedure		

3	<i>Documents certifying:</i>		
	o The IRB funding source		
	o Membership, appointment criteria, names and titles of the IRB members		
4	Guidelines used to issue the IRB decision		
5	List of documents required by the IRB for a new/ongoing clinical trial, to be submitted by the sponsor, or its representative		
6	The meeting procedure		
7	Documents clarifying the Voting system		
8	Document clarifying the procedure for issuing & reporting the final decision		
9	Documents archived and duration		
10	International Guidelines followed		
11	Agreement/contract for affiliation with other authorized IRB that includes monitoring mechanisms (only applicable for affiliations requests)		
<p><i>Summary of Documents submitted:</i></p> <ul style="list-style-type: none"> • Total number of members included in the IRB & Composition specialty: • Frequency of the IRB meeting: • Quorum Requirements: • How often is the IRB membership renewed? 			

Comments			
Evaluation Report Issued By:			
Approval of the IRB Committee	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Committee Review Date:			