



INFORMED CONSENT EVALUATION FORM

CGHMC RERB Protocol No.		Sponsor Protocol No.	
Protocol Title:			
Principal Investigators:		Co-investigator/s:	

INFORMED CONSENT DOCUMENT REVIEW	YES	NO	N/A	REVIEWER COMMENTS
1. Does the Informed Consent document state that the procedures are primarily intended for research?				
2. Are procedures for obtaining Informed Consent appropriate?				
3. Does the Informed Consent document contain comprehensive and relevant information?				
4. Is the information provided in the protocol consistent with those in the consent form?				
5. Is the expected duration of the study stated?				
6. Is the approximate number of participants stated?				



7. Are study related risks mentioned in the consent form?				
8. Is the language in the Informed Consent document understandable?				
9. Is the Informed Consent translated into the local language/dialect?				
10. Is there adequate protection of vulnerable participants?				
11. Are the different types of consent forms (assent, legally acceptable representative) appropriate for the types of study participants?				
Should assent be required? ☐ verbal assent (7 – 11 y/o) ☐ simplified assent (12 -14 y/o) ☐ co-sign (15 – 17 y/o)				
12. Is there a description of any reasonably foreseeable risks or discomfort to the subject?				
13. Is there a description of any benefits to the subject or to others which may reasonably be expected from the research?				
14. Is there a disclosure of appropriate alternative procedures or courses of treatment, if any, might be advantageous to the subject?				
15. Are names and contact numbers from the research team and the RERB in the informed consent?				



16. Does the ICF mention privacy & confidentiality protection?				
17. Is there any inducement for participation?				
18. Is there provision for medical / psychosocial support?				
19. Is there provision for treatment of study-related injury?				
20. Is there provision for compensation?				

B. Recommendation

DECISION:	☐ Approval	☐ Minor Revision
	☐ Major Revision/ Resubmission	☐ Disapproved
Comments (Identify items for revision)		
Reviewer's Name		Date
Signature		



中華崇仁總醫院暨醫學中心
CHINESE GENERAL HOSPITAL
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EXCEPTIONAL CARE WITHIN REACH



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