B I C O L U N I V E R S I T Y
C o l l e g e o f M e d i c i n e
Institutional Review Board
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ISO 9001:2008
Certificate No. TUV 100 05 1782

INFORMED CONSENT EVALUATION FORM (FORM 2.4)

IRB Protocol No.		Date (D/M/Y):	
Protocol Title:			
Principal Investigators:			

A. INFORMED CONSENT DOCUMENT REVIEW

1.	Does the Informed Consent document state that the procedures are primarily intended for research? ☐ Yes ☐ No	Comment:
2.	Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐ No	Comment:
3.	Does the Informed Consent document contain comprehensive and relevant information? ☐ Complete ☐ Incomplete	Comment:
4.	Is the information provided in the protocol consistent with those in the consent form? ☐ Consistent ☐ Inconsistent	Comment:
5.	Are study related risks mentioned in the consent form? ☐ Complete ☐ Incomplete	Comment:
6.	Is the language in the Informed Consent document understandable? ☐ Clear ☐ Unclear	Comment:
7.	Is the Informed Consent translated into the local language/dialect? ☐ Clear ☐ Unclear	Comment:
8.	Is there adequate protection of vulnerable participants? ☐ Yes ☐ No	Comment:
9.	Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants? ☐ Complete ☐ Incomplete	Comment:
10.	Are names and contact numbers from the research team and the IRB in the informed consent? ☐ Yes ☐ No	Comment:
11.	Does the ICF mention privacy & confidentiality protection? ☐ Yes ☐ No	Comment:

12. Is there any inducement for participation?
☐ Unlikely ☐ Likely
Comment:

13. Is there provision for medical / psychosocial support?
☐ Appropriate ☐ Inappropriate
Comment:

14. Is there provision for treatment of study-related injuries
☐ Appropriate ☐ Inappropriate
Comment:

15. Is there provision for compensation?
☐ Appropriate ☐ Inappropriate
Comment:

B. Recommendation

DECISION :	☐ Approval	☐ Minor Revision
	☐ Major Revision/ Resubmission	☐ Disapproval

Comments (Identify items for revision.)	

Reviewer's Name		Date:	

Signature :	