

**ANNEX 1 : AF/01-011/02**

**Study Assessment Form**

Protocol Number :		Date (D/M/Y):	
Protocol Title :			
Principal Investigators:		Professional Registration No, if applicable:	
Institute:		Contact No.	
Co – investigator(s):		Contact No.	
Total No. of Participants:		No. of Study site:	
Funding Agency:		Contact No.	
Duration of the Study:		Status: <input type="checkbox"/> New <input type="checkbox"/> Revised <input type="checkbox"/> Amended	
Reviewer's name :		Contact No.	
Type of the Study :	<input type="checkbox"/> Intervention <input type="checkbox"/> Epidemiology <input type="checkbox"/> Observation <input type="checkbox"/> Document based <input type="checkbox"/> Individual based <input type="checkbox"/> Genetic <input type="checkbox"/> Social Survey <input type="checkbox"/> Others, specify.....		
Review Status:	<input type="checkbox"/> Regular <input type="checkbox"/> Expedited <input type="checkbox"/> Emergency		
Description of the Study in brief: Mark whatever applied to the study. <input type="checkbox"/> Randomized <input type="checkbox"/> Stratified Randomized <input type="checkbox"/> Open-labeled <input type="checkbox"/> Double blinded <input type="checkbox"/> Placebo controlled <input type="checkbox"/> Treatment controlled <input type="checkbox"/> Cross-over <input type="checkbox"/> Parallel <input type="checkbox"/> Interim Analysis <input type="checkbox"/> Use of Tissue samples <input type="checkbox"/> Use of Blood samples <input type="checkbox"/> Use of genetic materials <input type="checkbox"/> Multicenter study <input type="checkbox"/> Screening <input type="checkbox"/> Descriptive Brief the study design and the statistic used: Study Objectives: ..... ..... ..... ..... .....			

Mark and comment on whatever items applicable to the study.

<b>Study Protocol</b>		
1	Objectives of the Study <input type="checkbox"/> clear <input type="checkbox"/> unclear <input type="checkbox"/> not mentioned	What should be improved?
2	Need for Human Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
3	Methodology: <input type="checkbox"/> clear <input type="checkbox"/> unclear	What should be improved?
4	Background Information and Data <input type="checkbox"/> sufficient <input type="checkbox"/> insufficient	Comment:
5	Sufficient number of participants? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
6	Inclusion Criteria <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate <input type="checkbox"/> Not provided	Comment:
7	Exclusion Criteria <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate <input type="checkbox"/> Not provided	Comment:
8	Discontinuation and Withdrawal Criteria <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate <input type="checkbox"/> Not provided	Comment:
9	Data collection tools <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate <input type="checkbox"/> Not provided	Comments
<b>Qualifications of Investigators and study sites</b>		
10	Are Qualification and experience of the Participating Investigators	Comment:

	appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> CV not attached	
11	Facilities and infrastructure of Participating Sites <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate <input type="checkbox"/> Site not mentioned	Comment:
12	Disclosure or Declaration of Potential Conflicts of Interest <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
13	Is there a Physician if the PI is non Physician <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable	Comments:
<b>Study Participation and Informed Consent</b>		
14	Risks and Benefits Assessment <input type="checkbox"/> acceptable <input type="checkbox"/> unacceptable	Comment:
15	Involvement of Vulnerable Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
16	Voluntary, Non-Coercive Recruitment of Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
17	Are blood/tissue samples sent abroad? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
18	Contact Persons for Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
19	Privacy & Confidentiality <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
20	Inducement for Participation	Comment:

	<input type="checkbox"/> Unlikely <input type="checkbox"/> Likely	
21	Provision for Medical / Psychosocial Support <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate <input type="checkbox"/> Not mentioned	Comment:
22	Provision for Treatment of Study-Related Injuries <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate <input type="checkbox"/> Not mentioned	Comment:
23	Provision for Compensation <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate	Comment:
24	Are procedures for obtaining Informed Consent appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
25	Is there an informed consent information to be provided for the participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments
26	Contents of the Informed Consent clear <input type="checkbox"/> clear <input type="checkbox"/> unclear	Comment:
27	Language of the Informed Consent <input type="checkbox"/> clear <input type="checkbox"/> unclear	Comment:
28	Information contents for the informed consent adequate <input type="checkbox"/> Adequate <input type="checkbox"/> Inadequate	Comments:
29	Is the informed consent information translated into local language <input type="checkbox"/> Yes <input type="checkbox"/> No	
30	Form for signature to ensure the administration of informed consent form, witness and person conducting informed consent form	Comments:

	<input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate <input type="checkbox"/> Not available	
<b>Community involvement and Impact</b>		
31	Community Consultation <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
32	Involvement of Local Researchers and Institution in the Protocol Design, Analysis and Publication of Results <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable	Comment:
33	Contribution to Development of Local Capacity for Research and Treatment <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable	Comment:
34	Benefit to Local Communities <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
35	Availability of similar Study / Results <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know	Comment:

**Reviewer Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_