

Protocol Number	

Protocol Title:	Date (m/d/y):	
TTOLOCOL TILLE.	Date (III/u/y).	
Di i II II I		
Principal Investigator		
A. Informed Consent Document Review		
1. Does the Informed Consent document	Comments / What should be improved?	
state that the procedures are primarily		
intended for research?		
☐ Yes ☐ No		
2. Are procedures for obtaining Informed	Comments / What should be improved?	
Consent appropriate?		
☐ Yes ☐ No		
3. Does the Informed Consent document	Comments / What should be improved?	
contain comprehensive and relevant		
information?		
☐ Yes ☐ No		
A. Objective of the Study		
B. Reason for inviting the respondents		
C. Procedures involve (e.g. accomplishment		
of a survey form, how many pages, how long		
will it take to finish)		
4. Is the information provided in the protocol	Comments / What should be improved?	
Consistent with those in the consent form?		
☐ Consistent ☐ Inconsistent		
5. Are study related risks mentioned in the	Comments / What should be improved?	
consent form?		
☐ Yes ☐ No		
6. Is the language in the Informed Consent	Comments / What should be improved?	
document understandable?		
☐ Yes ☐ No		
7. Is the Informed Consent translated into the	Comments / What should be improved?	
local language/dialect?		
☐ Yes ☐ No		
8. Are there vulnerable participants?	Comments / What should be improved?	
☐ Yes ☐ No		

(assent, pati	fferent types of consent forms ent representative) appropriate s of study participants?	Comments / What should be improved?		
│ │ □ Appropria	te □Inappropriate □N/A			
10. Are names and contact numbers from the		Comments / What should be improved?		
Research tea	am & the REC in the Informed			
Consent?				
□ Yes	□ No			
11. Does the ICF provide privacy and		Comments / What should be improved?		
confidentiali	ty protection?			
☐ Yes	□ No			
12. Is there a	any undue inducement for	Comments / What should be improved?		
participation	1?			
☐ Yes	□ No			
13. Is there provision for		Comments / What should be improved?		
medical/psy	chosocial			
support?				
□ Ye □	No □ Not Applicable			
14. Is there provision for treatment of study-		Comments / What should be improved?		
related Injur				
☐ Yes	☐ No ☐ Not Applicable			
15. Is the amount paid to participants stated?		Comments / What should be improved?		
□ Ye □	No 🗆 Not Applicable			
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16. Is there an option/right to withdrawal at		Comments / What should be improved?		
any time without consequences by the participants?				
Yes	□ No			
□ res	□ NO			
B. Recommer	ndation			
Decision: □ Approval □ Minor Modification □ Major Modification/Resubmission □ Disapproval				
Reviewer's				
Name:				
	Signature above	printed name	Date (M/D/Y)	