Northwestern State University
Institutional Review Board
Continuing Review Form

Directions: The purpose of the continuing review form is to review the approved protocol, after each 12-month period that the protocol is active ("active" means human subjects are still being recruited and data is still being collected from the subjects).
Each section of the form below contains information on the Continuing Review Request. Please read and complete each section carefully; a form missing information (or otherwise incomplete) will be returned for revision.
If you wish to report an adverse event, fill out the Adverse Events Report form.

Research		
Title of Project:		
Protocol # ID:		
Original Approval Date:		
Current Completion Date:		
Personal Information		
Principal Investigator (PI)	First Name:	Last Name:
PI NSU Email:		
PI Phone Number:		
Faculty Advisor (if applicable)	First Name:	Last Name:
Faculty Advisor NSU Email:		
Faculty Advisor Phone Number:		
Continuing Review of Approved Protocol		
For this approved protocol, do you wish to extend the current completion date for another 12 months?	◯ No	◯ Yes
Are you making any changes to the protocol as approved?	◯ No	◯ Yes
Please explain any changes and/or the reason/s for extension:		
NOTE: If you wish to make changes to the protocol as approved, you must also fill out and submit the Amendment Request Form.		

Assessment of the Approved Protocol				
Risks to subjects are minimized by using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk.	◯ YES	◯ NO	◯ N/A	
Risks to subjects are minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	◯ YES	◯ NO	◯ N/A	
Risks to subjects are reasonable to both: • anticipated benefits, if any, to subjects; and • the importance of the knowledge that may reasonably be expected to result.	◯ YES	◯ NO	◯ N/A	
Subject Selection				
Selection of subjects is equitable to the purposes of the research and the setting in which the research will be conducted.	◯ YES	◯ NO	◯ N/A	
Selection of subjects (i.e., inclusion and exclusion criteria) based on the protocol and the setting in which it will be conducted.	◯ YES	◯ NO	◯ N/A	
The recruitment process minimizes the potential for undue influence/coercion.	◯ YES	◯ NO	◯ N/A	
Compensation – neither the amount of payment nor the proposed method and timing of disbursement is coercive or presents potential for undue influence.	◯ YES	◯ NO	◯ N/A	
Recruitment materials are appropriate.	◯ YES	◯ NO	◯ N/A	
Informed Consent				
Informed consent is sought from each prospective subject or the subject's legally authorized representative and appropriately documented in accordance with, and to the extent required by 45 CFR §46.116, 45 CFR §46.117, 21 CFR §50.25, and 21 CFR §50.27 as applicable.	◯ YES	◯ NO	◯ N/A	*(For Exempt Review studies, informed consent is not required but is recommended by the NSU IRB for all protocols, if appropriate)*
Subject Protections				
The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. *For minimal risk studies, NSU IRB requires investigators conducting <u>clinical investigations</u> to, at a minimum, have a DSM plan.*	◯ YES	◯ NO	◯ N/A	

The research plan makes adequate provisions to protect the privacy of subjects.	◯YES	◯NO		
The research plan makes adequate provisions to maintain the confidentiality of data.	◯YES	◯ NO		
The research **does** involve subjects likely to be vulnerable to coercion or undue influence, including: children, prisoners, pregnant women, mentally disabled persons, economically / educationally disadvantaged persons, students, and non-native speakers of English.	◯YES	◯ NO		
If YES, the research plan **does** include <u>adequate</u> safeguards to protect their rights and welfare.	◯YES	◯NO		*If "No," additional safeguards:*
<u>Final Recommendation</u> (select ONE): ◯Approve ◯Approved Conditionally ◯Disapprove ◯Table <u>Reason(s) for recommendation</u>:				

Certification

I certify that the information provided on this form is complete and accurate. I agree to accept responsibility for the ethical conduct of this study. I also agree to notify the NSU IRB, within 10 business days after the end of all human subject recruitment and data collection activities, that the study has closed. In addition, I agree that all data collected from the human subjects will be stored securely and maintained for a minimum of 3 years from the date of the study close. Finally, I certify that I do not have any conflict of interest with this study.

Signatures (NOTE: PI and Faculty Sponsor--Type full name and date)

Principal Investigator: Date:

Faculty Sponsor (if applicable): Date:

*Approving Agent: Date:

*NOTE: The Approving Agent must sign this form with their digital signature, but only on the <u>final</u> version of the document. Once the e-signature is added, the form cannot be revised or changed in any way. The final version of the form--with the digital signature--is forwarded to the NSU IRB for the formal protocol review.