LIBERTY IRB, Inc.
A CENTRAL INDEPENDENT REVIEW BOARD

Full Accreditation

PROTOCOL INFORMATION SHEET

PLEASE TELL US ABOUT THE RESEARCH TO BE CONDUCTED:			
1.	Protocol Number and Version Date:		
2.	Title of Study:		
3.	Is this research Investigator initiated?	Yes	No
4	Sponsor Name:		
5.	Does the site have a written agreement with the sponsor that addresses medical care for research participants with a research-related injury, when appropriate?	Yes	No
6.	Does the sponsor conduct research site monitoring visits?	Yes	No
6a.	If #6 was answered "No" does the sponsor conduct monitoring activities remotely?	Yes	No
6b.	If #6 or 6a was answered "Yes" does the site have a written agreement with the sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the site?	Yes	No
7.	Does the site have a written agreement with the sponsor that the sponsor promptly reports to the site findings that could affect the safety of participants or influence the conduct of the study? * Checking yes signifies a written statement from the investigator or clinical research organization that contracts obligate the sponsor to send routine and urgent data and safety monitoring reports to the investigator or organization conducting the research.	Yes	No

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8.	Does the site have a written agreement with the sponsor about plans for disseminating findings from the research and the roles that researchers and the sponsor will play in the publication or disclosure of results?	Yes	No
9.	Does the site have a written agreement with the sponsor that the investigator or site will be notified of results directly affecting subject safety that occur or are realized after the study has ended so that the site can consider informing participating?	Yes	No
10	Will the PI (or research team) receive recruitment bonuses? ***If yes, please explain. Note: If this changes during the study Liberty IRB must be notified.***	Yes	No
11.	Is there a CRO involved in this study?	Yes	No
11a.	Name of CRO (if applicable)		
12.	Has this research been disapproved or terminated by another IRB prior to submission to Liberty IRB? ***(If yes, please submit a copy of disapproval/termination letter.)***	Yes	No
13.	Is this research federally funded entirely or in part? ***If there is a grant, please provide either a copy or a summary of the grant.***	Yes	No
14.	Does this research involve an Investigational New Drug (IND) or Biologic?	Yes	No
14a.	Please provide IND # ***(If IND # is not listed in protocol, you must provide copy of FDA approval letter.)***		
15.	Does this research involve a Device?	Yes	No

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	ONLY ANSWER QUESTIONS 15A, B, C, OR D IF YOUR RESEARCH INVOLVES A DEVICE.		
15a.	Does the device require an IDE?	Yes	No
15b.	If 15a is answered yes, please provide IDE # ***(If IDE # is not listed in protocol, you must provide copy of FDA approval letter.)***		
15c.	If an IDE is not applicable, does the device have a 510(k)? ***Please provide 510(k)#***	Yes	No
15d.	If there is not an IDE or 510(k), is the device exempt? ***If yes, please submit Device Exempt Checklist.***	Yes	No
16.	Does this research involve any type of Gene Transfer? ***(If yes, please provide proof of IBC review)***	Yes	No
17.	Will this research enroll any subjects from the following "vulnerable" categories? (*Check all that apply)* _____Mentally Disabled _____Handicapped _____Pregnant Woman _____Children _____Limited/Non-readers or Educationally Disadvantaged _____Economically Disadvantaged _____Prisoners _____Military personnel _____Others (indicate) ***When some or all participants are vulnerable, please attach a description of additional safeguards included to protect their rights and welfare.***	Yes	No

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18.	Will you be enrolling any employees of Research Site? ***If yes, you must include language in consent or obtain separate Employee Consent Form from Liberty.***	Yes	No
19.	Will you be enrolling students? ***If yes, you must include language in consent regarding whether responses will affect grade, and whether participation is mandatory.***	Yes	No
20.	a. Is the informed consent required to be signed? b. Do documents other than consent (i.e. surveys, diaries) require a direct identifier? (e.g. names, Social Security numbers, patient numbers, address, telephone numbers) ***If yes, indicate how subjects will be protected:***	Yes Yes	No No

21. If the research involves children(individuals who have not reached the legal age to consent to the treatments or procedures in the research): please attach a description of the provisions for permission of parents and guardians proposed:

- The permission of both parents is required if both parents are alive, known, competent, reasonably available, and have legal responsibility for the care and custody of the child. Otherwise the permission of one parent is required
- The permission of one parent is sufficient, even if the other parent is alive, known competent, reasonably available, and shares legal responsibility for the care and custody of the child.
- Include whether assent will be obtained from all children, some children, or no children. If assent is not required for all please include a description of which children are not required to assent and explain why.
- If assent will be obtained, indicate whether assent will be documented and if so, how.

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21a.	If applicable, provide a description of which individuals under state or local law can consent on behalf of the child to general medical care. (DHHS/FDA definition of "guardian") (*Note: Individuals who are not parents must meet this criterion to provide permission for a child to take part in research)*		
22.	Will this study enroll subjects who cannot read? (if yes, see below) *Liberty IRB requires an impartial witness to the consent process for subjects who cannot read. Please note that study personnel are not considered impartial witnesses.* ***Please describe your consent process in on a separate sheet of paper and attach to this*** *application.*	Yes	No
23.	Will compensation be provided to study participants?	Yes	No

23a.	Indicate compensation for each visit:	
	Visit Number	Compensation
	Screening	$
		$
		$
		$
		$
	Total Amount	$
23b.	If yes, indicate when subjects will be compensated: _____End of Study _____Quarterly _____Annually _____ At each Visit _____Other (indicate):	

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24.	Has a request been made for a waiver of the requirement to obtain written documentation of consent? **If so, please provide a script of the information to be disclosed to participants.**

NAME OF PERSON COMPLETING FORM (CONTACT PERSON FOR QUESTIONS):	
Name:	
Title:	
Phone Number:	
Fax Number:	
Email Address:	
Date:	Signature: