



LIBERTY IRB

An Independent Central IRB



Protocol Information Sheet

<i>Please tell us about the research to be conducted:</i>			
1.	Protocol Number and Version Date:		
2.	Title of Study:		
3.	Is this research Investigator initiated?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
6.	Does the sponsor conduct research site monitoring visits?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
6a.	If #6 was answered "No" does the sponsor conduct monitoring activities remotely?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
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?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
10.	Is there a CRO involved in this study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
10a.	Name of CRO (if applicable)		



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11.	Has this research been disapproved or terminated by another IRB prior to submission to Liberty IRB? <i>(If yes, please submit a copy of disapproval/termination letter.)</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
12.	Is this research federally funded entirely or in part?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
13.	Does this research involve an Investigational New Drug (IND) or Biologic?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
13a.	Please provide IND # <i>(If IND # is not listed in protocol, you must provide copy of FDA approval letter.)</i>		
14.	Does this research involve an Investigational Device?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
14a.	Please provide IDE # <i>(If IDE # is not listed in protocol, you must provide copy of FDA approval letter.)</i>		
15.	Does this research involve any type of Gene Transfer? <i>(If yes, please provide proof of IBC review)</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
16.	Will this research enroll any subjects from the following “vulnerable” categories? <i>(Check all that apply)</i> <div style="display: flex; flex-wrap: wrap; padding-left: 20px;"> <div style="width: 50%;"><input type="checkbox"/> Mentally Ill</div> <div style="width: 50%;"><input type="checkbox"/> Mentally Disabled</div> <div style="width: 50%;"><input type="checkbox"/> Nursing Home Resident</div> <div style="width: 50%;"><input type="checkbox"/> Institutionalized</div> <div style="width: 50%;"><input type="checkbox"/> Terminally Ill</div> <div style="width: 50%;"><input type="checkbox"/> Hospitalized</div> <div style="width: 50%;"><input type="checkbox"/> Pregnant Woman</div> <div style="width: 50%;"><input type="checkbox"/> Limited/Non-readers</div> <div style="width: 50%;"><input type="checkbox"/> Indigent</div> <div style="width: 50%;"><input type="checkbox"/> Children</div> <div style="width: 50%;"><input type="checkbox"/> Prisoners</div> <div style="width: 50%;"><input type="checkbox"/> Students</div> <div style="width: 50%;"><input type="checkbox"/> Employees of Research Site</div> <div style="width: 50%;"><input type="checkbox"/> Military personnel</div> <div style="width: 50%;"><input type="checkbox"/> Others (indicate)</div> </div>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
17.	Will the research use any direct identifiers? (e.g. names, Social Security numbers, patient numbers, address, telephone numbers) If yes, Indicate how subject will be protected:	Yes <input type="checkbox"/>	No <input type="checkbox"/>
18.	<p>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:</p> <ul style="list-style-type: none"> 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 		



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children are not required to assent and explain why. <ul style="list-style-type: none"> • If assent will be obtained, indicate whether assent will be documented and if so, how. 															
19.	Will this study enroll subjects who cannot read? (if yes, see below) <i>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.</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>												
20.	Will compensation be provided to study participants?	Yes <input type="checkbox"/>	No <input type="checkbox"/>												
20a.	Indicate compensation for each visit: <div style="text-align: center; margin-bottom: 5px;">Visit Number</div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="padding: 2px;">Screening</td></tr> <tr><td style="padding: 2px;"> </td></tr> <tr><td style="padding: 2px;"> </td></tr> <tr><td style="padding: 2px;"> </td></tr> <tr><td style="padding: 2px;"> </td></tr> <tr style="background-color: #FFD700;"><td style="padding: 2px;">Total Amount</td></tr> </table>	Screening					Total Amount	Compensation <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="padding: 2px;">\$</td></tr> <tr><td style="padding: 2px;">\$</td></tr> <tr><td style="padding: 2px;">\$</td></tr> <tr><td style="padding: 2px;">\$</td></tr> <tr><td style="padding: 2px;">\$</td></tr> <tr style="background-color: #FFD700;"><td style="padding: 2px;">\$</td></tr> </table>		\$	\$	\$	\$	\$	\$
Screening															
Total Amount															
\$															
\$															
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20b.	If yes, indicate when subjects will be compensated: <input type="checkbox"/> End of Study <input type="checkbox"/> Quarterly <input type="checkbox"/> Annually <input type="checkbox"/> At each Visit <input type="checkbox"/> Other (indicate):														
21.	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:



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