

PRINCIPAL INVESTIGATOR INFORMATION SHEET

<i>Please provide information about the Investigator and the Research Site:</i>			
1.	Principal Investigator Name:		
2.	Is this a multi-site study in which the investigator is the lead investigator	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2a.	If yes please include a description of the management of information obtained in multi-site research that might be relevant to the protection of subjects, such as: <ul style="list-style-type: none"> Unanticipated problems involving risks to subjects or others. Interim Results Protocol Modifications 		
2.	Will there be any Sub-Investigators participating in this trial?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2a.	Sub-Investigator Name(s):		
3.	PI Degree(s):	PI Specialty:	
3a.	Is the PI Board certified in his/her specialty? <i>Please provide a copy of this certification.</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4.	Name of Primary Research Site: Address: <i>*List all additional research sites on Additional Research Location Form</i>		
4a.	Research center phone number:	Research center fax number:	
4b.	Principal Investigator 24 Hour / Emergency Contact number:		
4c.	Principal Investigator email address:		
5.	Study Coordinator name:		
5a.	Study Coordinator phone number:		
5b.	Study Coordinator fax number:		
5c.	Study Coordinator email address:		
6.	Indicate site preference for receiving documents: <input type="checkbox"/> U.S. Mail <input type="checkbox"/> Email		

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7.	Has PI ever been convicted of a crime, disciplined by public or private medical organization, disciplined by a licensing authority, or is the PI currently involved in any such proceeding? <i>(if yes, provide explanation)</i>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
8.	Will this research be conducted in Massachusetts?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
9.	<p>With the following definitions in mind: Immediate Family – means spouse and dependent children Financial Interest Related to Research – means financial interest in the sponsor, product or service being tested, or competitor of the sponsor or product or service being tested.</p> <p>Does the PI, PI’s immediate family have any of the following? <i>Check all that apply</i></p> <p><input type="checkbox"/> Ownership interest, stock option or other financial interest related to the research unless it meets one of the following:</p> <ul style="list-style-type: none"> • Does not exceed \$25,000 for FDA regulated studies or \$10,000 for DHHS regulated studies when aggregated for the immediate family • Publicly traded on a stock exchange • No arrangements have been entered into where value of the ownership interests will be affected by the outcome the research • Does not exceed 5% interest in any one single entity when aggregated for the immediate family. <p><input type="checkbox"/> Compensation related to the research unless it meets one of the following:</p> <ul style="list-style-type: none"> • Does not exceed \$25,000 for FDA regulated studies or \$10,000 for DHHS regulated studies in the past year when aggregated for the immediate family • No arrangement has been entered into where the amount of compensation will be affected by the outcomes of the research <p><input type="checkbox"/> Proprietary interest related to the research including but not limited to, a patent, trademark, copyright or licensing agreement</p> <p><input type="checkbox"/> Board or executive relationship related to the research regardless of compensation</p> <p><i>Note: If any of the above is checked, describe on a separate sheet of paper the financial interest and any steps planned to prevent the financial interest from interfering with the design, conduct, or reporting of the research, including interfering with the protection of participants.</i></p>		
10.	<p>While this protocol is active, how many of the following will the PI supervise:</p> <p>Physician Sub-Investigators; _____ Sites: _____</p>		
11.	<p>How many of the following does the PI currently supervise:</p> <p>Open Research Studies: _____ Approximate Number of Active Subjects: _____</p>		

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12.	Does the principal Investigator have sufficient <u>time</u> to conduct and complete the research?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
13.	<p>Liberty IRB requires all investigators and their research staff to be qualified by training and experience to conduct research. Clinical research training should include training on Code of Federal Regulations, training in Human Research Subject Protection, and training on Good Clinical Practice (GCPs). Indicate whether or not research training was completed by each of the following:</p> <p>Principal Investigator <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Primary Study Coordinator <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Secondary Study Coordinator <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Sub-Investigator _____ <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Sub-Investigator _____ <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Sub-Investigator _____ <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Sub-Investigator _____ <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Other: _____ <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Other: _____ <input type="checkbox"/> Yes <input type="checkbox"/> No</p>		
14.	<p>How long has the PI been conducting research?</p> <p><input type="checkbox"/> New Site <input type="checkbox"/> < 1 yr. <input type="checkbox"/> 1-5 yrs. <input type="checkbox"/> >5yrs</p>		
15.	Does the Principal Investigator have adequate numbers of qualified staff to perform research related activities?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
15a.	Indicate number of active protocols, including those only in follow up.		
15b.	Indicate number of research coordinators.	<p>Full Time: _____</p> <p>Part Time: _____</p>	
16.	Does the Principal Investigator have adequate facilities to conduct the research?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
17.	Does the Principal Investigator have access to a population that will allow recruitment of the necessary number of subjects?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
18.	Does the Principal Investigator have a process in place to ensure that all persons assisting with research are adequately informed about the protocol and their research related duties and functions?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
19.	Does the Principal Investigator have access to medical or psychological resources that participants might require as a consequence of the research?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
20.	Will you be using a Site Management Organization (SMO) for this study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
20a.	If yes, name of organization:		

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	<input type="checkbox"/> Employees of Research Site <input type="checkbox"/> Military personnel <input type="checkbox"/> Others (indicate)		
28.	When some or all participants are vulnerable, please attach a description of additional safeguards included to protect their rights and welfare.		
29.	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"/>
30.	Will consent be obtained from a legally authorized representative for some or all subjects?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
30a.	If question 30 is answered yes, describe which individuals are authorized under state or other law to consent on behalf of a prospective subject to his or her participation in the procedures involved in this proposed research. <i>(Note: All persons deemed to be "legally authorized representatives" must meet this criterion prior to signing the informed consent.)</i>		
31.	Please include a detailed explanation of the proposed consent process (or attach a copy of the consent process SOP) including answers to the following: <ul style="list-style-type: none"> • Who will provide consent or permission (e.g. subject, parent, parents, or legally authorized representative)? • What is the waiting time, if any, between informing the prospective subject and obtaining the consent? • What steps will be taken to minimize the possibility of coercion or undue influence? • What are the languages used by those obtaining consent? • How is the consent process documented? 		
32.	If a request for a waiver of the requirement to obtain written documentation of consent is requested, please include a script of the information to be disclosed to participants.		
33.	Will the research involve children? (<i>individuals who have not reached the legal age to consent to the treatments or procedures involved in research</i>)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
33a.	If question 33 is answered as yes, provide a description (age) under which individuals are not considered to have reached legal age under state or other law to consent to the proposed treatments or procedures involved in the proposed research. <i>(Note: Regulations for children involved in research apply to all persons meeting this criterion.)</i>		

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33a.	<p>If question 33 is answered yes, 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 “guardians”) (<i>Note: individuals who are not parents must meet this criterion to provide permission for a child to take part in the research</i>)</p>		
<p>Liberty IRB recommends that investigators consult with legal counsel to answer questions 30-33, to be sure they are in compliance with state and local law. In states where this determination is not explicit, please submit a written statement from legal counsel explaining state and/or other law regarding this matter.</p>			
34.	<p>Please include a description of the site-specific steps taken to protect the privacy interests of subjects (<i>i.e. being left alone, limiting access to themselves, and limiting access to their information</i>)</p>		
35.	<p>Please include a description of the site-specific steps taken to maintain the confidentiality of data. (<i>i.e. where the data will be stored, how it is stored, and how access to the data is controlled</i>).</p>		
36.	<p>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></p>	<p>Yes <input type="checkbox"/></p>	<p>No <input type="checkbox"/></p>
37.	<p>Who will discuss informed consent with study subjects? (<i>check all that apply</i>) <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Sub-Investigator <input type="checkbox"/> Study Coordinator</p>		
38.	<p>Will compensation be provided to study participants?</p>	<p>Yes <input type="checkbox"/></p>	<p>No <input type="checkbox"/></p>

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38a.	<p style="text-align: center;">Indicate compensation for each visit: Visit Number</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%; padding: 2px;">Screening</td> <td style="width: 20%; padding: 2px;">\$</td> </tr> <tr> <td style="padding: 2px;"> </td> <td style="padding: 2px;">\$</td> </tr> <tr> <td style="padding: 2px;"> </td> <td style="padding: 2px;">\$</td> </tr> <tr> <td style="padding: 2px;"> </td> <td style="padding: 2px;">\$</td> </tr> <tr style="background-color: #FFD700;"> <td style="padding: 2px;">Total Amount</td> <td style="padding: 2px;">\$</td> </tr> </table>	Screening	\$		\$		\$		\$	Total Amount	\$	<p style="text-align: center;">Compensation</p>
Screening	\$											
	\$											
	\$											
	\$											
Total Amount	\$											
38b.	<p>If yes, indicate when subjects will be compensated:</p> <p> <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): </p>											
39.	<p>Please include a copy of the contract with the sponsor describing the arrangements for payments for treatments for research related injury.</p>											
40.	<p>Indicate if any of the following methods will be used for subject recruitment:</p> <p> <input type="checkbox"/> Personal contact (practice) <input type="checkbox"/> Referrals (<i>Liberty IRB does not permit referral fees</i>) <input type="checkbox"/> Advertising (<i>All recruitment materials must be IRB approved</i>) <input type="checkbox"/> Other, please describe: </p>											
41.	<p>Will any of the following recruitment materials be utilized? (<i>check all that apply</i>)</p> <p> <input type="checkbox"/> Brochure <input type="checkbox"/> Newspaper <input type="checkbox"/> Letter <input type="checkbox"/> Posting <input type="checkbox"/> TV <input type="checkbox"/> Web site <input type="checkbox"/> Public Service Announcement <input type="checkbox"/> Radio <input type="checkbox"/> Other _____ </p> <p>* A copy of all materials that were checked need to be included in the submission.</p>											

Name of Person Completing Form (contact person for questions):	
Name:	
Title:	
Phone Number:	
Fax Number:	
Email Address:	
Date:	Signature: