

Initial Review Site Application

Instructions: Please read and complete all sections carefully. Any missing or inconsistent information may result in a delay of your submission. Please fill in all sections exactly as you would like them to appear on all documents.

Sponsor:	Protocol #:
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Principal Investigator's Name:		
Medical License #(s):	State(s):	Expiration Date(s):

Primary Research Facility

Site Name:		
Address:		
City:	State:	Zip Code:
Phone Number:	Fax:	
Email:		
Website (if available):		
In your professional opinion is the community attitude towards research positive? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Will additional Facilities be used in the conduct of this research? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please complete the Additional Facility Form.		
Is the primary research facility under the jurisdiction of another IRB? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please complete the IRB Waiver.		

IRB Contact Person:

Who will be responsible for communication with Compass IRB?		
Name:	Title:	
Business Name:		
Email:		
Is this contact at the same address as the P.I.? <input type="checkbox"/> Yes <input type="checkbox"/> No If No, please fill in the information below.		
Should IRB correspondence be sent to the address below? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Address:		
City:	State:	Zip Code:
Phone Number:	Fax:	
If the person listed above is not the Study Coordinator, please provide the Study Coordinator's name:		
Will any member(s) of the staff other than the P.I., the IRB Contact Person and/or the Study Coordinator be submitting documents to the IRB? <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," please list the names of those staff members:		

Conflict of Interest:

Does the P.I., the P.I.'s immediate family, the study staff or the study staff's immediate family have a relationship with the study sponsor or other study related entities that could be considered a Conflict of Interest as defined by Compass IRB standards (e.g. does not exceed \$10,000 USD)? Yes* No

Please see FAQs at www.compassirb.com for all parameters concerning Compass IRB Conflicts of Interest standards.

**If yes, please submit a written description of 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.*

Emergency Precautions

Is the P.I. and/or research staff available to participants on a 24-hour basis?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is this primary research facility equipped to handle emergencies?	<input type="checkbox"/> Yes <input type="checkbox"/> No
How close is the nearest emergency facility?	
What is the name of this facility?	

Resources

How long has the P.I. been conducting clinical research?	_____ years _____ months
How many open research studies does the P.I. have?	_____
Number of research personnel overseen by the P.I.:	_____
Number of research facilities overseen by the P.I.:	_____
Approximate number of active research subjects:	_____
Has the P.I. and his/her staff had training in human research protection?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Additional Information about the Principal Investigator:

If any of the below questions are answered "Yes." Please attach appropriate supporting documentation.	
Has the site or any investigator been audited by the FDA in the last three (3) years?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the P.I. ever received an FDA 483 or Warning Letter?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the P.I. ever had his/her license suspended or revoked?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the P.I. had any other professional sanctions?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Population

Please fill in all blanks below with percentage values.			
What is the approximate demographic population of your community (specifically, your town / city / surrounding area, not just your practice or anticipated study population)?			
_____ %: Male	_____ %: Caucasian	_____ %: African Descent	_____ %: Asian
_____ %: Female	_____ %: Middle Eastern	_____ %: Pacific Islander	_____ %: Latino
Age:	_____ %: Native American	_____ %: Other	
_____ %: 0-17 yrs.			
_____ %: 18-64 yrs.			
_____ %: 65+ yrs.			

State Laws

Are there any State/local laws that you are aware of that might impact/ influence the conduct of this study? (For example, use of legally authorized representatives, involvement of children in research, or guardianship)	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "yes," please note below:	

Subjects

How many subjects does the P.I. plan to enroll in this study?	
Will you be enrolling vulnerable subjects (pregnant women, fetuses, neonates, children, prisoners, persons unable to consent)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "yes," please describe additional safeguards that are in place to protect their rights and welfare (or please attach appropriate documentation) and please also provide information on how you will verify whether or not the category of individuals may require an Legally Authorized Representative, guardian or witness and whom can act in that capacity in your jurisdiction (according to your local laws):	
How does the P.I. plan to recruit subjects for this research?	
<input type="checkbox"/> Advertising <input type="checkbox"/> Subject Database <input type="checkbox"/> P.I.'s Clinical Practice <input type="checkbox"/> Referrals <input type="checkbox"/> Other: _____	
Are recruitment materials or subject materials enclosed for review? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If "Yes," check all that are enclosed.	
<input type="checkbox"/> Print Advertisement <input type="checkbox"/> Letter <input type="checkbox"/> Brochure <input type="checkbox"/> T.V. Advertisement* <input type="checkbox"/> Radio Advertisement* <input type="checkbox"/> Public Service Announcement <input type="checkbox"/> Other: _____	
** It is highly recommended that you submit a script for these items to be approved before recording.	

Informed Consent

Please list the P.I.'s contact info as it should appear in the Informed Consent.
Phone Number: Emergency (After Hours) Number: Pager Number:
If main office number and after hours number are the same, please explain how the study staff would be alerted in the event that a subject was calling with an after hours emergency?
Please list the names of those staff members that may be presenting the consent?

In the space below, provide us a detailed explanation of your consent process or please attach a copy of your consent process; include the person who will conduct the consent discussion, the person who will be expected to grant permission or consent, any waiting period between informing the potential subject and obtaining consent, steps taken to minimize the possibility of coercion or undue influence, the language to be used by those obtaining consent, the language understood by the prospective subject or legally authorized representative and the information to be communicated to the prospective subject or the legally authorized representative

Translations

Will non-English speaking subjects be enrolled?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Will the P.I. need a translated Informed Consent?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "Yes," will you need Compass IRB to provide the translated consent?	<input type="checkbox"/> Yes <input type="checkbox"/> No* <input type="checkbox"/> N/A
If so, please list language(s) needed:	
*Please note that if you choose to use a private translation vendor for your ICF, you must submit a certified translation to Compass IRB for review and approval prior to using for the consent of non-English speaking subjects.	

Compensation

Will you be compensating subjects for participation in this study?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
If "No," skip ahead to next section. If "Yes," when will the subject receive his/her compensation? <input type="checkbox"/> At each completed study <input type="checkbox"/> At the end of the subject's participation in the study. <input type="checkbox"/> Other (Please specify) _____			
Subjects will be compensated as detailed below: (please feel free to list more than one visit per line if compensation amount is the same for each).			
Visit Name	Amount	Visit Name	Amount
EXAMPLE: Visit(s) 1-4	\$ 25.00 each	Visit(s) 5-10	\$ 45.00 each
Screening Visit	\$		\$
	\$		\$
	\$		\$
	\$		\$
	\$		\$
Is there any additional information or forms of compensation that you need to disclose to Compass IRB? <input type="checkbox"/> Yes <input type="checkbox"/> No			
If "Yes," please explain below:			

Additional Information

Is there any additional information you need to share with Compass IRB?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "Yes," please take this space to share with us?	

Principal Investigator's Responsibility Statement

Please **initial each line** to verify your understanding of each of the following statements:

- _____ I have read and understand the research protocol and all supporting documentation. I will personally conduct or supervise this clinical study as the protocol dictates. I will adhere to GCPs, Federal Regulations and any additional laws that apply while overseeing this study.
- _____ All research activity will be conducted according to the approved study plan. I understand that any and all changes to the approved research must be reported to Compass IRB in a prompt manner and approved by the Board prior to implementing any changes to the protocol or Informed Consent, regardless how minor, except to eliminate apparent immediate hazards to subjects.
- _____ I will promptly report any and all Unanticipated Problems and Protocol Deviations as required by Compass IRB.
- _____ The Informed Consent will be presented to all subjects by me or a qualified member of my staff. The subject will have adequate time in a private environment to read, review and consider the Informed Consent. A member of my staff or I will be available to answer any questions or concerns subjects have regarding their participation in the study. All subjects will be given as much time as they feel is needed to make a decision to participate in this study.
- _____ I also am aware that it is my responsibility to conduct research in an environment that is conducive to subject safety. With that said, I recognize that if I choose to enroll subjects that could be considered a member of a vulnerable population, I will take the appropriate extra measures to ensure that he/she is fully aware of what is involved with their participation and the potential risks associated with the research.
- _____ I agree to make myself available to all subjects, should they request to speak to me directly at any point during their participation regarding any questions or concerns they may have regarding their involvement in the study.
- _____ As Principal Investigator, I will ensure that the language in my final ICF regarding compensation for injury to subjects matches the language in my clinical trial agreement for this study and if there is a discrepancy, I will promptly notify the IRB in order to modify the ICF language.
- _____ As Principal Investigator, I will ensure my Clinical Trial Agreement provides that I will be notified of findings of study monitors that could affect the safety of participants, affect the willingness of participants to continue participation, influence the conduct of the study, or alter the IRB's approval to continue the study and I will promptly notify the IRB of any such finding.
- _____ As Principal Investigator, I will ensure my Clinical Trial Agreement provides that I will be notified of the study results that directly affects the subject's safety or medical care

I, the Principal Investigator, hereby certify that all the information in this document is accurate and that I am fully aware of my responsibilities with regard to the conduct of this study.

Principal Investigator Signature

Date