LIBERTY IRB, Inc.
A CENTRAL INDEPENDENT REVIEW BOARD

Full Accreditation

# PRINCIPAL INVESTIGATOR INFORMATION SHEET

| PLEASE PROVIDE INFORMATION ABOUT THE INVESTIGATOR AND THE RESEARCH SITE: | | | |
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| 1. | Principal Investigator Name: | | |
| 2. | Does the PI have an obligation to use another IRB for any site in this study?<br>***If yes, please complete Waiver of Authorization Form*** | Yes | No |
| 3. | 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? ***( If yes, provide explanation)*** | Yes | No |
| 4. | Has the PI received an FDA warning letter or Health Canada Inspection Report within the past 5 years?<br>***If yes, please provide explanation*** | Yes | No |
| 5. | Is this a multi-site study in which the investigator is the lead investigator | Yes | No |
| 5a. | 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:<br>• Unanticipated problems involving risks to subjects or others.<br>• Interim Results<br>• Protocol Modifications | | |
| 6. | Will there be any Sub-Investigators participating in this trial? | Yes | No |
| 6a. | Has any Sub-Investigator ever been convicted of a crime, disciplined by public or private medical organization, disciplined by a licensing authority, or is the Sub-Investigator currently involved in any such proceeding? ***If yes, provide explanation*** | Yes | No |
| 6b. | Sub-Investigator Name(s): | | |


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| 7. | PI Degree(s): | PI Specialty: | |
| 7a. | Is the PI Board certified in his/her specialty?<br>***Please provide a copy of this certification.*** | Yes | No |
| 8. | Name of Primary Research Site:<br>Address:<br><br>**List all additional research sites on Additional Research Location Form* | | |
| 8a. | Research center phone number: Research center fax number: | | |
| 8b. | Principal Investigator 24 Hour / Emergency Contact number: | | |
| 8c. | Principal Investigator email address: | | |
| 9. | Study Coordinator name: | | |
| 9a. | Study Coordinator phone number: | | |
| 9b. | Study Coordinator email address: | | |
| 10. | What type of facility is this site?<br>☐ Research Clinic<br>☐ Medical Office<br>☐ Hospital<br>☐ Other: | | |

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| 11. | **Due to the Public Health Service rule on individual financial conflict of interest changing to the DHHS rule on August 24, 2012 the disclosure thresholds have been changed.**<br><br>With the following definitions in mind:<br>***Immediate Family*** – means spouse and dependent children<br>***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.<br><br>Does the PI, PI's immediate family have any of the following? ***Check all that apply***<br><br>____Ownership interest, stock option or other financial interest related to the research unless it meets one of the following:<br>• Does not exceed $5,000 when aggregated for the immediate family<br>• Publicly traded on a stock exchange<br>• No arrangements have been entered into where value of the ownership interests will be affected by the outcome the research<br>• Does not exceed 5%interest in any one single entity when aggregated for the immediate family.<br><br>____Compensation related to the research unless it meets one of the following:<br>• Does not exceed $5,000 in the past year when aggregated for the immediate family<br>• Does not exceed 5% interest in any one single entity when aggregated for the immediate family.<br>• No arrangement has been entered into where the amount of compensation will be affected by the outcomes of the research<br><br>____Proprietary interest related to the research including but not limited to, a patent, trademark, copyright or licensing agreement<br><br>____Board or executive relationship related to the research regardless of compensation<br>***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.*** |

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| | ***In addition to initial disclosure, the Investigator must notify Liberty IRB whenever his/her financial interests in the study change. Financial conflict of interest should be disclosed to the IRB in writing via a letter from the Investigator to the IRB Chairman.** | | |
| 12. | While this protocol is active, how many of the following will the PI supervise:<br><br>Sub-Investigators; _____ Sites: _____ | | |
| 13. | How many of the following does the PI currently supervise:<br><br>Open Research Studies: _____ Approximate Number of Active Subjects: _____<br><br>**It is important to note that Liberty requires a Site Management Plan to be submitted when 100+ subjects are actively enrolled or there are 10+ open studies. This plan should explain the various steps taken, staff involvement, etc. that ensures the PI is able to effectively conduct this amount of research while still ensuring subject safety. <u>PI credentials will not be approved without this plan submitted.</u>** | | |
| 14. | Does the principal Investigator have sufficient <u>time</u> to conduct and complete the research? | Yes | No |
| 15. | Does the Principal Investigator have adequate <u>facilities</u> to conduct the research? | Yes | No |
| 16. | Does the Principal Investigator have <u>access to a population</u> that will allow recruitment of the necessary number of subjects? | Yes | No |
| 17. | Does the Principal Investigator have <u>access to medical or psychological resources</u> that participants might require as a consequence of the research? | Yes | No |

## PRINCIPAL INVESTIGATOR INFORMATION SHEET

18. 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 (CFR), training in Human Research Subject Protection (HRSP), and training on Good Clinical Practice (GCPs). **CCRC/ CPI Stands for Certified Clinical Research Coordinator/ Certified Principal Investigator.**
Indicate whether or not research training was completed by each of the following:

| TYPE OF TRAINING | CFR/ HSRP | GCP | CCRC/CPI * | COMPLETED IN THE LAST 5 YEARS? | |
|---|---|---|---|---|---|
| Principal Investigator | | | | Yes | No |
| Primary Study Coordinator | | | | Yes | No |
| Secondary Study Coordinator | | | | Yes | No |
| **TYPE OF TRAINING** | **CFR/ HSRP** | **GCP** | **CCRC/CPI *** | **COMPLETED IN THE LAST 5 YEARS?** | |
| Sub-Investigator: | | | | Yes | No |
| Sub-Investigator: | | | | Yes | No |
| Sub-Investigator: | | | | Yes | No |
| Sub-Investigator: | | | | Yes | No |
| Sub-Investigator: | | | | Yes | No |
| Sub-Investigator: | | | | Yes | No |

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*Continued… Indicate whether or not research training was completed by each of the following:*

| TYPE OF TRAINING | CFR/ HSRP | GCP | CCRC/CPI * | COMPLETED IN THE LAST 5 YEARS? | |
|---|---|---|---|---|---|
| Sub-Investigator: | | | | Yes | No |
| Sub-Investigator: | | | | Yes | No |
| Other: | | | | Yes | No |
| Other: | | | | Yes | No |

Note: Liberty IRB is a participating organization in the Collaborative Institutional Training Initiative (CITI). Investigators using Liberty as their central IRB can meet the training requirement through CITI. Please email or call for information on how to access the CITI training if you are interested.

*** Satisfies training requirements**

**** If all training has not been completed within the last 5 years the PI, Sub-I or staff member may still participate in this research; however, a refresher training course must be completed within 6 months..**

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| 19. | How long has the PI been conducting research? ◯ New Site ◯ < 1 yr. ◯ 1-5 yrs. ◯ >5yrs | | |
| 20. | Does the Principal Investigator have adequate numbers of qualified staff to perform research related activities? | Yes | No |
| 20a. | Indicate number of research coordinators. | Full Time: _____ Part Time: _____ | |
| 21. | 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 | No |

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| 22. | Does the PI oversee multiple locations for this study? ***If so, you must submit the Additional Research Location Form.*** | Yes | No |
| 22a. | Does the site have a Site Management Plan to explain how the PI will manage the multiple locations? ***If yes, please provide a copy.*** **A Site Management Plan for this purpose should explain how the PI manages multiple locations, multiple Sub-Investigators and whether the sites are in a drivable distance. The PI is ultimately responsible for the study conduct.** | Yes | No |
| 23. | Does the Principal Investigator have a process in place for storage, control, and dispensing of unlicensed test articles so that they are used only in approved research protocols and under the direction of approved investigators? | Yes | No |
| 24. | Describe any negative local attitude toward medical research that might affect this study: | | |
| 25. | Are there laws governing medical research in your state? | Yes | No |
| 25a. | Have the laws governing research in your state changed in the last year? | Yes | No |
| 25b. | Will this study be conducted in California? In Massachusetts? ***If yes, please circle the state in which the study will be conducted.*** | Yes | No |

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| 26. | Describe the population to be recruited for this research: ***(These numbers should add up to 100%)***<br>_____% African American/Black ____ % Asian ____% Caucasian<br>_____ % Pacific Islander ____ % Native American<br>_____% Middle Eastern ____ % Aboriginal peoples of Canada<br>% Other (list) _____<br>*Note: This information may be estimated based on practice location.*<br>Ethnicity: ***(These numbers should add up to 100%)***<br>____ % Hispanic or Latino ____ % Not Hispanic or Latino | | |
| 27. | Please indicate the language(s) of the subjects the PI intends to enroll. *(The consent form must be in a language easily understood by the subject, and all consent form translations must be approved by Liberty IRB.)*<br>_____ English _____ Spanish _____ French _____ Other (specify) _____ | | |
| 28. | Will consent be obtained from a legally authorized representative for some or all subjects? | Yes | No |
| 28a. | If question 28 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. *(Note: All persons deemed to be "legally authorized representatives" must meet this criterion prior to signing the informed consent.)*<br><br>**Liberty IRB recommends that investigators consult with legal counsel to answer this question 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** | | |

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| 29. | Please include a detailed explanation of the proposed consent process (or attach a copy of the consent process SOP) including answers to the following:<br>• Who will provide consent or permission (e.g. subject, parent, parents, or legally authorized representative)?<br>• What is the waiting time, if any, between informing the prospective subject and obtaining the consent?<br>• What steps will be taken to minimize the possibility of coercion or undue influence?<br>• What are the languages used by those obtaining consent?<br>• How is the consent process documented? |
| 30. | Privacy refers to being free from being observed or disturbed by other people. Please note the site-specific steps taken to protect the privacy interests of subjects ***(Check all that apply)***<br>_____ Consenting and research activities are performed in a private room<br>_____ Subjects are given time alone or only with family if requested<br>_____ Subject is free from being observed or disturbed by other people<br>_____ Separate room or drapes used when exams are performed or when subjects must Disrobe<br>_____ Only necessary information is collected<br>_____ Other privacy precautions: |
| 31. | Please note the site-specific steps taken to maintain the confidentiality of data *(i.e. where the data will be stored, how it is stored, and how access to the data is controlled)* ***(Check all that apply)***<br>_____ When feasible, identifiers will be removed from study-related information<br>_____ Data stored in paper format will be kept in a secure location; access is limited to only those individuals required to access for study requirements<br>_____ Electronic file access is limited to only those individuals required to access for study requirements<br>_____ Other confidentiality precautions: |
| 32. | Who will discuss informed consent with study subjects? *(check all that apply)*<br>_____ Principal Investigator _____ Sub-Investigator _____ Study Coordinator |

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| 33. | Are the Investigator and sub-investigators aware that although a participant is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights?<br><br>Yes _____ No _____ |
| 34. | Indicate if any of the following methods will be used for subject recruitment:<br><br>_____ Personal contact (practice)<br>_____ Referrals *(Liberty IRB does not permit referral fees)*<br>_____ Advertising *(All recruitment materials must be IRB approved)*<br>_____ Other, please describe: |
| 35. | Will any of the following recruitment materials be utilized? *(check all that apply)*<br><br>_____ Brochure _____ Newspaper _____ Letter _____ Posting<br>_____ TV _____Web site _____ Public Service Announcement<br>_____ Radio _____ Twitter/Facebook<br>_____ Other:<br><br>* A copy of all materials that were checked need to be included in the submission. |
| 36. | If your site is involved in a multi-site study, provide any site-specific additions or changes you would like made to your documents (e.g. change in compensation language, addition of CA specific language, or any other language your site requires). |


## PRINCIPAL INVESTIGATOR INFORMATION SHEET

| PLEASE TELL US WHO SHOULD BE BILLED FOR THIS REVIEW: | | |
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| 37. | Principal Investigator Name: | |
| 38. | Name of person to whom invoice should be sent: | |
| 39 | Billing Address: | |
| 40. | Billing Contact phone number: | Billing Contact fax number: |
| 41. | Billing Contact email address: | |
| 42. | Describe any special billing instructions: | |

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