

WIRB[®]

WESTERN INSTITUTIONAL REVIEW BOARD[®]
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OHRP/FDA Parent Organization number: IORG0000432 • IRB registration number: IRB00000533



WIRB INITIAL REVIEW SUBMISSION REQUIREMENTS for International Sites *(research taking place outside the United States and Canada)*

Requests for review of research taking place solely in the United States (and its territories) or Canada, can be made on WIRB's normal initial review submission form; however, **if the research sites will be outside the U.S. or Canada, complete this form.**

In addition to WIRB's usual requirements for review of research in the U.S. and Canada, the Board considers the following information for international reviews:

- Information about the local laws related to human subjects research, if applicable.
- Information about the local culture.
- Information about the local culture provided by one or more knowledgeable local persons attending the meeting in person, via teleconference, or via videoconference, when possible.

WIRB prefers to partner with a local IRB or ethics committee for oversight of international sites. This form will request information about local IRBs or ethics committees. If there is no local IRB or ethics committee available, the form will ask you to provide an explanation of the arrangement for local oversight of this research.

Consent form considerations: When WIRB enters into a dual IRB agreement with another IRB or ethics committee to oversee the research, all changes to the consent form will be subject to approval by both IRBs. When the WIRB-approved consent form is translated by the other IRB, WIRB will not routinely conduct its own verification of the translation (as is customary for translations for studies conducted *in* the U.S. and Canada) unless the circumstances warrant it. Translated versions of the consent form are not required to display a WIRB approval stamp.

The following is a general list of items needed by WIRB to begin the review process for your research study. You will need to submit a submission form with each protocol you submit for review. If you have questions, call 1-800-562-4789 or e-mail clientservices@wirb.com for assistance.

ALL INITIAL REVIEW REQUESTS for international sites must include one copy of the following:

- Current version of WIRB initial review submission form for international sites (posted at www.wirb.com)
- Protocol*
- Current professional license for Principal Investigator, showing the expiration date*
- Curriculum Vitae (CV) for Principal Investigator and each Sub-Investigator*
- Consent form*
- Other materials to be provided to the subjects which are not included in the protocol, such as advertisements, questionnaires, subject diaries, etc.* (Any commercially available validated instruments cited in the protocol that are used without modification are not listed individually on the Certificate of Approval; however, approval of the protocol does extend to the uses of such industry standard forms as described in the approved protocol.)

If a DRUG/BIOLOGIC study, a copy of the following:

- Investigator's Drug Brochure*
- Background Information for Food Supplements*
- FDA Form 1572 (if applicable)
- Documentation from sponsor or FDA verifying the IND (Investigational New Drug) number, if one is required for the research.* If an IND is not required, provide the reason why in writing.
- For gene transfer studies subject to RAC review, please submit the RAC correspondence, Appendix M responses, and IBC approval and minutes (if available). If the IBC review has yet to occur, please provide a date for the intended review and contact information for your NIH-OBA registered IBC.

If a DEVICE study, provide device manual and ONE of the following:

- Unredacted FDA Letter granting the Investigational Device Exemption (IDE)*; OR
- Letter from sponsor stating that the study is a non-significant risk device study;* OR
- Letter explaining why the investigation is exempt from the IDE requirements under 21CFR 812.2(c) or otherwise exempt.*

*Material may be omitted if WIRB is already in receipt of a current version.



Initial Review Submission Form for International Sites

(research taking place outside the United States and Canada)

Instructions:

- Handwritten copies of this form are accepted, but WIRB encourages submitters to submit a typed version to prevent errors and delays due to legibility problems.
- All questions must be answered. "N/A" is only an option where indicated.
- If the contact information provided in this form changes during the life of the study, please provide the updated information to us.
- Your review may be delayed if we need to obtain clarification from you because information listed below differs from the information listed in the additional submitted documents.
- Please check the WIRB web site to ensure you are completing the most current version of this form – form is updated at least once per year.

Sponsor _____

Sponsor Protocol No. _____

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| I. PRINCIPAL INVESTIGATOR (PI) INFORMATION: Please provide information about the person legally responsible for the conduct of the research. WIRB must be assured that the investigator can personally oversee the conduct of the research and the protection of human subjects. [21 CFR 56.102 (h)] | | | |
| 1. | PI Name Surname: _____, Given name: _____ | Gender: <input type="checkbox"/> M <input type="checkbox"/> F | |
| 1a. | PI Company Name: _____ | | |
| 1b. | PI Mailing Address: Street: _____ City: _____ Province or region (if applicable): _____ Postal code (if applicable): _____ Country: _____ | | |
| 1c. | PI Phone: _____ | PI Fax: _____ | PI E-mail: _____ |
| 1d. | How would the PI prefer to receive study documents? (check one) <input type="checkbox"/> Fax <input type="checkbox"/> E-mail <input type="checkbox"/> Regular Mail | | |
| 1e. | PI Degree(s): _____ | PI Specialty(ies): _____ | |
| 1f. | If this research will be conducted through an organization which has a contract to use WIRB for IRB services, please provide the name of the organization: _____ | | N/A <input type="checkbox"/> |
| 2. | Study Coordinator Name Surname: _____, Given name: _____ | | Gender: <input type="checkbox"/> M <input type="checkbox"/> F |
| 2a. | Study Coordinator Phone: _____ | Study Coordinator Fax: _____ | Study Coordinator E-mail: _____ |

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| 2b. | <p>Does the study coordinator need to receive a copy of the regulatory documents in addition to the copy sent to the PI? *If Yes, How would the coordinator prefer to receive study documents? (check one) <input type="checkbox"/> Fax <input type="checkbox"/> E-mail</p> <p>Note: Study documents are also available on the WIRB web site to users who establish a WIRBNet account (go to www.wirb.com and click "LOGIN" in the upper right to set up an account). If additional study contacts would like access to study documents, you may grant them access to view the documents by clicking "Manage View Rights to your account" after logging in to WIRBNet.</p> | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3. | <p>Would you like Continuing Review Report Forms (CRRFs) sent to a contact other than the PI? (If your study is approved, Continuing Review Report Forms that must be completed will be mailed to the address provided above for the PI unless you provide an alternate name and address below). *If Yes, complete question 3a below.</p> | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3a. | <p>CRRF contact name and mailing address: Surname: _____, Given name: _____</p> <p>Location Name: _____</p> <p>Street: _____ City: _____ Province or region (if applicable): _____ Postal code (if applicable): _____ Country: _____</p> <p>Phone: _____ E-mail: _____</p> <p><i>Note: The information collected above is used solely for the delivery of CRRFs; if the person named above is not listed on any of the questions in this form that ask "How would the contact prefer to receive documents from WIRB?", they will not receive other study documents.</i></p> | | |
| 4. | <p>Has the PI ever received a citation from a government agency for non-compliance that has not been previously submitted to WIRB? *If Yes, please attach all relevant correspondence and reports.</p> | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 5. | <p>Has the PI ever had any research at their site suspended or terminated by an IRB <i>other than WIRB</i>? *If Yes, complete question 5a.</p> | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 5a. | <p>Has the instance of suspended and/or terminated research referenced above been reported to WIRB prior to this submission? *If No, you must attach information about the incident and its outcome.</p> | Yes <input type="checkbox"/> | *No <input type="checkbox"/> |
| 6. | <p>Has the PI ever been convicted of a crime, disciplined by a public or private medical organization, disciplined by a licensing authority, or is the PI currently the subject of such a proceeding? *If Yes, complete question 6a.</p> | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 6a. | <p>Has the conviction and/or discipline referenced above been reported to WIRB prior to this submission? *If No, you must attach information about the incident and its outcome.</p> | Yes <input type="checkbox"/> | *No <input type="checkbox"/> |

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| 7. | Have any of the <i>sub-investigators or study staff</i> ever been convicted of a crime, disciplined by a public or private medical organization, disciplined by a licensing authority, or are any currently the subject of such a proceeding? *If Yes, complete question 7a. | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 7a. | Has the <i>sub-investigators or study staff</i> conviction and/or discipline referenced above been reported to WIRB prior to this submission? *If No, you must attach information about the incident and its outcome. | Yes <input type="checkbox"/> | *No <input type="checkbox"/> |
| 8. | <i>Licensing Information:</i> Please fill in the information requested below and attach legible copies of all pertinent <u>current</u> licenses and registrations (if not on file at WIRB). If necessary, please enlarge the copy of the license for legibility. | | |
| 8a. | Medical or Professional License number: Country: State/province (if applicable): Expiration Date (if applicable): | N/A <input type="checkbox"/> | |
| 9. | Please attach a signed copy of each of the following (if applicable): <ul style="list-style-type: none"> • U.S. FDA form 1572; • Your country's equivalent. | N/A <input type="checkbox"/> | |
| 10. | Financial conflict of interests: If any of the following are true for the PI, PI's immediate family (spouse and dependent children), the study staff, or the study staff's immediate family, complete the <i>Financial Interest Disclosure Form</i> provided at the end of this submission form. <input type="checkbox"/> Yes , one or more of the following are true: (check all that apply and then complete the additional disclosure page at the end of this form) <ul style="list-style-type: none"> <input type="checkbox"/> Has a financial interest in the research with value that cannot be readily determined (for example, stock that is not publicly traded); <input type="checkbox"/> Has a financial interest in the research with value that exceeds \$10,000 other than payments for conducting the trial as outlined in the clinical trials agreement; <input type="checkbox"/> Has a financial interest in the research with value that exceeds 5% ownership; <input type="checkbox"/> Has received or will receive compensation with value that may be affected by the outcome of the study; <input type="checkbox"/> Has a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement; <input type="checkbox"/> Has received or will receive payments other than payment for the conduct of clinical research from the sponsor that exceed \$10,000 in the last 365 days; <input type="checkbox"/> Is an employee of the agency or company sponsoring the research; <input type="checkbox"/> Is on the board of directors of the sponsor; <input type="checkbox"/> Has a financial interest that requires disclosure to the sponsor or funding source; or <input type="checkbox"/> Has any other financial interest that the investigator believes may interfere with his or her ability to protect subjects. <input type="checkbox"/> No , none of the above are true. | | |
| 11. | Will the PI (or research team) receive recruitment bonuses? (WIRB defines a recruitment bonus as an additional payment or incentive provided to the PI or staff dependent solely on a particular number of subjects being enrolled, or dependent on the speed at which subjects are enrolled. The term "payment or incentive" includes any items of value, such as direct payment, gift certificates, travel vouchers, physical items such as watches, etc.) *If Yes, report such incentives on the recruitment bonus disclosure form at the end of this submission form. | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |

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| 12. | Please confirm that if any proposals are made to enact <i>recruitment bonuses</i> during the course of this research study, that you will submit them as a change in research for prior IRB review (using WIRB's recruitment bonus disclosure form). <input type="checkbox"/> I confirm <input type="checkbox"/> Other (<i>explain</i>): _____ | | |
| 13. | For <u>this</u> protocol, how many of the following will the PI supervise? Sub-Investigators _____ Sites _____ Research Coordinator(s) _____ Projected Number of Enrolled Subjects: _____ (Do not leave any spaces blank; enter "NA" or "0" when appropriate) | | |
| 14. | How many of the following does the PI currently supervise? (total for all research projects) Open Research Studies _____ Sites _____ Physician Sub-Investigators _____ Research Coordinator(s) _____ Approx. Number of active subjects _____ (Do not leave any spaces blank; enter "NA" or "0" when appropriate) | | |
| 15. | Investigators must ensure each member of the research study team/staff (including the PI and sub-investigators) has had training in the protection of human subjects. Training must be completed prior to submission of this application and documentation must be kept at the site. Has each member of the team completed such training? <table style="float: right; border: none;"> <tr> <td style="text-align: center;">Yes <input type="checkbox"/></td> <td style="text-align: center;">No <input type="checkbox"/></td> </tr> </table> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | | |
| 15a. | Indicate what type(s) of training were completed: (mark at least one, and all that apply) <input type="checkbox"/> NIH online tutorial "Protecting Human Research Participants" <input type="checkbox"/> NCI Human Participant Protections Education for Research Teams <input type="checkbox"/> Collaborative Institutional Training Initiative (CITI) <input type="checkbox"/> WIRB-sponsored Investigator or GCP course <input type="checkbox"/> Academic/medical center's institutional human subject protection training requirements satisfied <input type="checkbox"/> N/A – this submission is for one of the following: <input type="checkbox"/> A Treatment IND or Treatment IDE <input type="checkbox"/> Non-research use of a Humanitarian Use Device <input type="checkbox"/> Other (<i>specify</i>): _____ HIPAA training alone is not sufficient. WIRB's expectation is that training include topics such as ethical principles related to human subject protections, federal regulations for protection of human subjects, and Good Clinical Practice. A list of potential sources, including web-based tutorials, books, and in-person training courses is available at www.wirb.com or by contacting WIRB's Client Services. | | |
| 16. | Will a Site Management Organization (SMO) or similar be involved in this research? If No, proceed to question 17. <table style="float: right; border: none;"> <tr> <td style="text-align: center;">Yes <input type="checkbox"/></td> <td style="text-align: center;">No <input type="checkbox"/></td> </tr> </table> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | | |
| 16a. | SMO Name: | | |
| 16b. | SMO Address: Street: City: Province or region (if applicable): Postal code (if applicable): Country: | | |

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| 16c. | SMO Contact Name Surname: _____, Given name: _____ | Gender: <input type="checkbox"/> M <input type="checkbox"/> F |
| 16d. | SMO Contact Phone: _____ | SMO Contact Fax: _____ |
| 16e. | How would the SMO contact prefer to receive documents from WIRB? (check one) <input type="checkbox"/> Fax <input type="checkbox"/> E-mail <input type="checkbox"/> Regular Mail | |

II. SPONSOR & PROTOCOL INFORMATION: Please tell us about the research to be conducted.

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| 17. | Protocol Number and Version Date: _____ | | |
| 18. | Protocol title: _____ | | |
| 19. | Is this research investigator-initiated? (i.e., no separate sponsor is involved) Please note, the Board routinely requires continuing review every six months (rather than once per year) for investigator-initiated research involving a clinical intervention. *If Yes, who is funding the research? _____ | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 20. | Is this research Phase I, Phase I/II, or are you requesting an exception from informed consent for emergency research based on the exception defined by federal regulation 21 CFR 50.24? Please note, because of the increased risk associated with these types of research, the Board routinely requires continuing review every six months, rather than once per year. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 21. | Will an independent data safety monitoring committee oversee the research? *If Yes, please indicate who WIRB may contact to obtain information about the findings of the committee: Name: _____ Company: _____ Title: _____ E-mail address: _____ Phone number: _____ | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 22. | If this protocol is substantially similar to one previously reviewed by WIRB, you may indicate the similar protocol(s) here: _____ _____ (WIRB support staff will provide the Board with information about the previous Board review, so that the previous decision of the Board can be taken into account when this research is reviewed.) | N/A <input type="checkbox"/> | |
| 23. | Has another IRB or ethics committee declined to review, tabled, deferred, disapproved or terminated this research study at your site prior to submission to WIRB? *If Yes, please provide the IRB/ethics committee correspondence. | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 24. | Is this study being transferred to WIRB from another IRB/ethics committee? *If Yes, please fill out the IRB Transfer form posted at www.wirb.com . | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |

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| 25. | Does the sponsor plan to submit the data to the United States Environmental Protection Agency (EPA)? *If Yes, WIRB will apply the additional requirements of the EPA regulations. | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 26. | Is this research funded by the U.S. government entirely or in part? If No, proceed to question 27. (There are additional regulatory requirements for investigators seeking approval of research funded by the U.S. government. A summary of the requirements is available at http://www.wirb.com/content/wirb_services_irbervices_fed.aspx .) | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 26a. | What United States federal agency(ies) is funding this research? | N/A <input type="checkbox"/> | |
| 26b. | Provide a copy of the complete grant (if applicable). | N/A <input type="checkbox"/> | |
| 26c. | If this grant funds multiple protocols, please list the protocols previously reviewed by WIRB. | N/A <input type="checkbox"/> | |
| 26d. | Provide the United States government federal contract (if applicable). | N/A <input type="checkbox"/> | |
| 27. | Does this research involve a Drug, Biologic or Dietary Supplement? If No, proceed to question 28. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 27a. | Provide the Investigational New Drug (IND) number assigned by the FDA: (Under most circumstances, WIRB requires an IND for research involving dietary supplements.) If an IND number is not available or if you do not plan to obtain one, you must attach an explanation; for example, study is not being conducted under an FDA New Drug Application (NDA), a copy of the FDA letter indicating an IND is not required, etc. | N/A <input type="checkbox"/> | |
| 27b. | Attach documentation from the sponsor or FDA verifying the IND number for this research. Indicate any that are attached: <input type="checkbox"/> FDA letter <input type="checkbox"/> Sponsor letter <input type="checkbox"/> IND number is in protocol or other sponsor-generated document. <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Already on file with WIRB (Copy not necessary if already on file with WIRB. Contact WIRB's Client Services for information.) | N/A <input type="checkbox"/> | |
| 27c. | Provide a copy of the Investigator's Drug Brochure (unless previously sent to WIRB), applicable package inserts, or the background information for food supplements. | N/A <input type="checkbox"/> | |
| 28. | Does this research involve an Investigational Device? *If Yes, proceed to question 28a. | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 28a. | You must provide one of the following: <ul style="list-style-type: none"> • Unredacted FDA letter granting an Investigational Device Exemption for the proposed use, • Letter from sponsor stating that the study is a non-significant risk device study, or • Letter explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2(c) or otherwise exempt. | N/A <input type="checkbox"/> | |

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| 29. | Does this research involve any form of gene transfer ? (i.e., experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human research participants) If No, proceed to question 30. | Yes <input type="checkbox"/> | | No <input type="checkbox"/> |
| 29a. | Has this been submitted to the Recombinant DNA Advisory Committee (RAC)? | Yes <input type="checkbox"/> | | No <input type="checkbox"/> |
| 29b. | If available, attach the Response to Appendix M of the National Institutes of Health (NIH) Guidelines. | | | N/A <input type="checkbox"/> |
| 29c. | If available, attach copies of the RAC correspondence regarding the protocol. | | | N/A <input type="checkbox"/> |
| 29d. | Has there been an Institutional Biosafety Committee (IBC) review? *If Yes, please attach the IBC recommendations. | *Yes <input type="checkbox"/> | | No <input type="checkbox"/> |
| 30. | Sponsor Name: | | | |
| 30a. | Sponsor Contact Name Surname: _____, Given name: _____ | Gender: <input type="checkbox"/> M <input type="checkbox"/> F | | |
| 30b. | Sponsor Contact Address: Street: City: Province or region (if applicable): Postal code (if applicable): Country: | | | |
| 30c. | Sponsor Contact Phone: | Sponsor Contact Fax: | Sponsor Contact E-mail: | |
| 30d. | How would the sponsor contact prefer to receive documents from WIRB? (check one) <input type="checkbox"/> Fax <input type="checkbox"/> E-mail <input type="checkbox"/> Regular Mail <input type="checkbox"/> N/A | | | |
| 30e. | Medical Monitor Name Surname: _____, Given name: _____ | Gender: <input type="checkbox"/> M <input type="checkbox"/> F | | |
| 30f. | Medical Monitor Phone: | Medical Monitor Fax: | Medical Monitor E-mail: | |
| 31. | Is a Contract Research Organization (CRO) involved in this research? If No, proceed to question 32. | Yes <input type="checkbox"/> | | No <input type="checkbox"/> |
| 31a. | CRO Name: | | | |
| 31b. | When a CRO is involved, WIRB routinely sends approval documents to the CRO <i>instead of the sponsor</i> , not to both. Would the sponsor contact like copies sent to them <i>in addition to the copies sent to the CRO contact</i> ? | Yes <input type="checkbox"/> | | No <input type="checkbox"/> |

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| 31c. | CRO Address: Street: City: Province or region (if applicable): Postal code (if applicable): Country: | | |
| 31d. | CRO Contact Name Surname: _____, Given name: _____ | | Gender: <input type="checkbox"/> M <input type="checkbox"/> F |
| 31e. | CRO Contact Phone: _____ | CRO Contact Fax: _____ | CRO Contact E-mail: _____ |
| 31f. | How would the CRO contact prefer to receive documents from WIRB? (check one) <input type="checkbox"/> Fax <input type="checkbox"/> E-mail <input type="checkbox"/> Regular Mail <input type="checkbox"/> N/A | | |

III. RESEARCH SITE LOCATIONS & INFORMATION (must match submitted 1572, if applicable): Please tell us where the research will take place by completing this section for each site. If you will be conducting the research at more than one site, complete and attach the Additional Site Listing form at the end of this document for each additional site. Each site listed below and on the 1572 will be listed on the consent form.

If site information changes during the course of the study, you will need to notify WIRB. Please request the necessary changes using the *Change In Research and Subject Recruitment (Ads) Submission Form* available on the WIRB web site.

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| 32. | <p>Site #1: (List only sites at which subjects will be seen; or, for federally funded research, list only the sites "engaged in research" according to the OHRP definition found here: http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html.)</p> <p>Name of Research Location: _____</p> <p>Physical Address: (must match box 3 of submitted 1572, if applicable)</p> <p>Street: _____</p> <p>City: _____</p> <p>Province or region (if applicable): _____</p> <p>Postal code (if applicable): _____</p> <p>Country: _____</p> | | | | | | | | | |
| 32a. | Site #1 Phone: _____ | | | | | | | | | |
| 32b. | <p>What type of facility is this site?</p> <table style="width: 100%;"> <tr> <td><input type="checkbox"/> Medical office</td> <td><input type="checkbox"/> Hospital</td> <td><input type="checkbox"/> University</td> </tr> <tr> <td><input type="checkbox"/> Psychiatric Institution</td> <td><input type="checkbox"/> Nursing home</td> <td><input type="checkbox"/> Other (specify): _____</td> </tr> <tr> <td><input type="checkbox"/> Research Clinic</td> <td><input type="checkbox"/> Dialysis Center</td> <td></td> </tr> </table> | <input type="checkbox"/> Medical office | <input type="checkbox"/> Hospital | <input type="checkbox"/> University | <input type="checkbox"/> Psychiatric Institution | <input type="checkbox"/> Nursing home | <input type="checkbox"/> Other (specify): _____ | <input type="checkbox"/> Research Clinic | <input type="checkbox"/> Dialysis Center | |
| <input type="checkbox"/> Medical office | <input type="checkbox"/> Hospital | <input type="checkbox"/> University | | | | | | | | |
| <input type="checkbox"/> Psychiatric Institution | <input type="checkbox"/> Nursing home | <input type="checkbox"/> Other (specify): _____ | | | | | | | | |
| <input type="checkbox"/> Research Clinic | <input type="checkbox"/> Dialysis Center | | | | | | | | | |
| 32c. | <p>What resources are available at this site to treat emergencies resulting from study-related procedures?</p> <p><input type="checkbox"/> BLS trained personnel</p> <p><input type="checkbox"/> ACLS trained personnel and crash cart</p> <p><input type="checkbox"/> Emergency drugs and supplies to stabilize subject until emergency personnel arrive</p> <p><input type="checkbox"/> Emergency response team within facility</p> <p><input type="checkbox"/> Call emergency response number</p> <p><input type="checkbox"/> Other (specify): _____</p> <p><input type="checkbox"/> N/A (explain): _____ and skip to question 32f.</p> | | | | | | | | | |

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| 36. | If there is not a local IRB or ethics committee, please provide an explanation of the arrangement for local oversight of this research: | | NA <input type="checkbox"/> | |
| 37. | Is this research currently ongoing? *If Yes, complete and attach the IRB Transfer Cover Letter Checklist & Summary Form available on the Download Forms page of www.wirb.com . | *Yes <input type="checkbox"/> | No <input type="checkbox"/> | |
| 38. | Are there any laws regarding human subject research in the country where the research will be conducted? *If Yes, please attach a copy of the laws and citations. (If No, you may skip to question 39.) WIRB may already have a copy of this information for the country on file; you may contact us to determine if this is the case. | *Yes <input type="checkbox"/> | No <input type="checkbox"/> | |
| 38a. | Are there any laws in this country addressing whether vulnerable populations such as indigenous persons, children, pregnant women, and cognitively impaired individuals be enrolled in research? *If Yes, please provide them. | *Yes <input type="checkbox"/> | No <input type="checkbox"/> | |
| 39. | Have there been any recent changes to laws governing medical research in your country/region? *If Yes, please provide whatever information you have. | *Yes <input type="checkbox"/> | No <input type="checkbox"/> | unknown <input type="checkbox"/> |
| 40. | What is the legal age of adulthood in this country for both males and females? (At what age are each allowed to make legal decisions for themselves?) | | | |
| 41. | Are there any professional codes (or medical ethics codes if applicable) that govern the conduct of researchers in this country? | | | |
| 42. | Are there requirements for compensating subjects who are injured as a result of participating in research? *If Yes, please attach copies of the applicable requirements and their citations. | *Yes <input type="checkbox"/> | No <input type="checkbox"/> | |
| 43. | <p>For most research being conducted at international sites, the Board conducts a teleconference with an individual who is familiar with the country or region where the research will be conducted in order to assess local context. This can be a member of the local IRB or ethics committee or another person who is knowledgeable about the research and the local community. Please identify a person who can be available for this teleconference:</p> <p style="margin-left: 20px;">Name of Contact: Surname: _____, Given name: _____</p> <p style="margin-left: 20px;">Title: _____</p> <p style="margin-left: 20px;">Contact Address: _____</p> <p style="margin-left: 40px;">Street: _____</p> <p style="margin-left: 40px;">City: _____</p> <p style="margin-left: 40px;">Province or region (if applicable): _____</p> <p style="margin-left: 40px;">Postal code (if applicable): _____</p> <p style="margin-left: 40px;">Country: _____</p> <p style="margin-left: 20px;">Contact Phone Number: _____</p> <p style="margin-left: 20px;">Contact E-mail Address: _____</p> | | | |

Initial Review Submission Form for International Sites

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| 44. | <p>What is the local attitude toward human subject research?</p> <p style="margin-left: 20px;"><input type="checkbox"/> Positive <input type="checkbox"/> Negative</p> <p>If other than positive, please explain:</p> |
| 45. | <p>Privacy Protections: Privacy is a subject's ability to control how other people see, touch, or obtain information about the subject. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, being observed while conducting personal behavior, or disclosing information about abortions, HIV status, illegal drug use, etc.</p> <p>What precautions will be used to ensure subject <i>privacy</i> is protected? (check all that apply)</p> <p><input type="checkbox"/> Use of drapes or other barriers for subjects who are required to disrobe.</p> <p><input type="checkbox"/> Research intervention is conducted in a private room.</p> <p><input type="checkbox"/> The collection of sensitive information about subjects is limited to the amount necessary to achieve the aims of the research, so that no unneeded sensitive information is being collected.</p> <p><input type="checkbox"/> Other (<i>specify</i>): _____</p> <p>_____</p> <p>_____</p> |
| 46. | <p>Confidentiality precautions: (Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information, or visual information such as photographs.)</p> <p>What precautions will be used to maintain the confidentiality of identifiable information? (check all that apply)</p> <p><input type="checkbox"/> Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.</p> <p><input type="checkbox"/> Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.</p> <p><input type="checkbox"/> Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.</p> <p><input type="checkbox"/> Whenever feasible, identifiers will be removed from study-related information.</p> <p><input type="checkbox"/> Because the research involves web-based surveys, precautions are in place to ensure the data is secure by using passwords and encryption.</p> <p><input type="checkbox"/> Audio and/or video recordings of subjects will be transcribed and then destroyed to eliminate audible identification of subjects.</p> <p><input type="checkbox"/> Other (<i>specify</i>): _____</p> |

Initial Review Submission Form for International Sites

WIRB®

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| | | | |
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| 49a. | If the research allows enrollment of pregnant women: WIRB reviews research according to the requirements of Federal Regulation 45 CFR 46. One section of that regulation (45 CFR 46.204 (h), (i), (j)) requires the IRB to make specific determinations whenever pregnant women are enrolled in research. If the research allows enrollment of pregnant women, you must assure the board of the following by signing in the space provided at the end of this form (question 64): <ul style="list-style-type: none"> • No inducements, monetary or otherwise, will be offered to terminate a pregnancy; • Individuals engaged in conducting the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and • Individuals engaged in conducting the research will have no part in determining the viability of a neonate. | N/A <input type="checkbox"/> | |
| 49b. | If some or all subjects will be cognitively impaired, describe how capacity for consent will be determined: <input type="checkbox"/> Capacity assessment using the following method or instruments: _____ <input type="checkbox"/> Other (specify): _____ | N/A <input type="checkbox"/> | |
| 50. | Does the protocol permit Legally Authorized Representatives (LARs) to provide consent to enroll adults who do not have the legal capacity to provide consent, and if so, do you intend to enroll such subjects? (Consult the protocol's inclusion and exclusion criteria to determine if the protocol allows enrollment of such subjects.) *If Yes, you must answer questions 50a, 50b, and 50c below. | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 50a. | How do you determine which individuals meet the criteria for being an LAR under your local law? (Advice from your legal counsel is strongly recommended to determine local law requirements.) _____ _____ | N/A <input type="checkbox"/> | |
| 50b. | Describe how you will verify that a given individual is qualified to serve as an LAR: <input type="checkbox"/> Request documentation of authorization. <input type="checkbox"/> Obtains verbal assurance from the LAR. <input type="checkbox"/> Other (specify): _____ | N/A <input type="checkbox"/> | |
| 50c. | If your local law regarding Legally Authorized Representatives is difficult to interpret, you may provide the Board with a letter from legal counsel which includes a statement such as the following: "The individuals who are authorized under state/provincial law to consent on behalf of a prospective subject to that subject's participation in the procedures involved in this research protocol are _____." _____ | See attached <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 51. | Who will conduct the consent discussion with the subject? (Check all that apply) <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Sub-investigator <input type="checkbox"/> Research coordinator <input type="checkbox"/> Other (specify): _____ | | |

Initial Review Submission Form for International Sites

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Investigator Surname: _____

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| 52. | <p>Please describe the circumstances and location of the consent process: (check all that apply)</p> <p><input type="checkbox"/> N/A, waiver of consent requested (please complete one of the following WIRB forms: "Request for a Waiver of Consent under the Common Rule And Waiver of Authorization under HIPAA" or, "Request for a Waiver of Consent for In Vitro Diagnostic Device Study Using Leftover Human Specimens that are Not Individually Identifiable." Both are available on the Download Forms page of www.wirb.com).</p> <p><input type="checkbox"/> In a private room</p> <p><input type="checkbox"/> In a waiting room</p> <p><input type="checkbox"/> In an open ward</p> <p><input type="checkbox"/> In a group setting</p> <p><input type="checkbox"/> In a group setting with follow up in a private room.</p> <p><input type="checkbox"/> In emergency situations. The process is as follows (explain here or attach a separate sheet): _____</p> <p>_____</p> <p>_____</p> <p><input type="checkbox"/> Online, in public, over the phone, or in another unusual situation. The process is as follows (explain here or attach a separate sheet): _____</p> <p>_____</p> <p>_____</p> <p><input type="checkbox"/> Other (<i>specify</i>): _____</p> <p>_____</p> <p>_____</p> |
| 53. | <p>How will you be sure there is sufficient opportunity for the subject to consider whether to consent? (check all that apply)</p> <p><input type="checkbox"/> Subjects will be allowed to take home the unsigned consent form for consideration prior to signing it. (WIRB requires subjects to be allowed to take home the consent form to consider unless the subject is hospitalized or for some other reason cannot go home.)</p> <p><input type="checkbox"/> Subjects will be allowed a waiting period of at least _____ hours to consider their decision.</p> <p><input type="checkbox"/> Other (<i>specify</i>): _____</p> <p>_____</p> |
| 54. | <p>Describe steps taken to minimize the possibility of coercion or undue influence: (check all that apply)</p> <p><input type="checkbox"/> There will not be any threat of harm or adverse consequences if the subject does not agree to participate in the study, and the information provided during the consent process will be presented in a balanced way with equal emphasis on all elements of consent (for example, there will not be over-emphasis of benefits or under-emphasis of risks).</p> <p><input type="checkbox"/> Other (<i>specify</i>): _____</p> <p>_____</p> <p>_____</p> |
| 55. | <p>Mark one of the following regarding waiver of rights during the consent process:</p> <p><input type="checkbox"/> The consent process will not involve the use of any language that appears to require the subject and/or their representative to waive legal rights, and the consent process will not involve the use of any language that releases or appears to release the sponsor, institution, investigator, or any of their agents from liability for negligence.</p> <p><input type="checkbox"/> Other (<i>specify</i>): _____</p> <p>_____</p> |

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| 56. | <p>As part of our accreditation, WIRB requires that the clinical trials agreement (CTA) between the sponsor and the investigator (or investigator's institution) and the approved consent form do not conflict with each other regarding the compensation for injury.</p> <p>Please indicate what method you will use to ensure that no subjects are enrolled unless the CTA and the WIRB-approved consent form are in agreement: (check any that apply)</p> <ul style="list-style-type: none"> <input type="checkbox"/> This is minimal risk research for which compensation for injury language in the consent form is not necessary. <input type="checkbox"/> There is no CTA for this research. <input type="checkbox"/> This research is funded by a United States government agency (such as NIH) that does not offer compensation for injury. <input type="checkbox"/> Upon receipt of WIRB approval documents, the PI will check the CTA against the WIRB-approved consent form and resolve any conflicts via a request for a consent form modification to WIRB and/or a modified CTA before enrolling subjects. <input type="checkbox"/> The sponsor or CRO has agreed to review the WIRB-approved consent document and resolve any conflicts via a request for a consent form modification to WIRB and/or a modified CTA before authorizing enrollment at this site. Provide name and signature of sponsor or CRO representative below, or attach written correspondence from the sponsor or CRO indicating who will take this responsibility. <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%; border-top: 1px solid black; padding-top: 5px;">Printed or Typed Name</div> <div style="width: 45%; border-top: 1px solid black; padding-top: 5px;">Company & title</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px; color: red;"> <div style="width: 45%; border-top: 1px solid red; padding-top: 5px;">Signature</div> <div style="width: 45%; border-top: 1px solid red; padding-top: 5px;">Date</div> </div> <p style="margin-top: 5px;"><i>(Please note that if you are filling out this form in Word, you'll need to print this page, obtain the signature, and either fax it to us or scan the signed page and e-mail it to us.)</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> The PI is affiliated with an institution which has required compensation for injury language (attach a copy of the language). <input type="checkbox"/> The PI's hospital, university or medical center has a contract with WIRB for IRB services, and it has an established process for ensuring that the compensation for injury language in the CTA and in the consent form do not conflict. Name of Institution: _____ <input type="checkbox"/> Other (explain): _____ |
| 57. | <p>Check any of the following methods that the PI will use to recruit subjects for this study:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Advertising (<i>All recruitment materials must be approved by WIRB before use</i>) <input type="checkbox"/> From a database for which subjects have given prior permission to be contacted for research studies <input type="checkbox"/> From Personal Contact (for example, patients, students) <input type="checkbox"/> Referrals [<i>Offering or accepting payment to medical professionals or research staff for referring patients to research studies (finder's fees) is NOT allowed by WIRB. Payments to subjects for referring others may be considered by the Board on a case-by-case basis.</i>] <input type="checkbox"/> Other (specify): _____ <p style="margin-top: 10px;">U.S. SITES: PLEASE NOTE – for HIPAA compliance, you may need an authorization from the subject or a waiver of authorization before you can use or disclose identifiable health information for research screening or recruitment purposes. This may affect your ability to recruit subjects into this study. For more information on HIPAA requirements for research and additional HIPAA-related forms, go to www.wirb.com.</p> |

Initial Review Submission Form for International Sites

WIRB®

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| 58. | Please confirm that there are no plans to pay <i>referral fees</i> to medical providers or to subjects for referral of subjects to this research study. (Referral fees are fees paid to persons outside of the research to provide names of possible subjects.) <input type="checkbox"/> I confirm <input type="checkbox"/> Other (<i>explain</i>): _____ | | |
| 59. | Are recruitment materials or subject materials attached? *If Yes, check all that are attached: <input type="checkbox"/> Newspaper <input type="checkbox"/> Letter <input type="checkbox"/> Brochure <input type="checkbox"/> Web Site <input type="checkbox"/> Public Service Announcement <input type="checkbox"/> **Video (<i>recordings will not be reviewed without scripts</i>) <input type="checkbox"/> Posting <input type="checkbox"/> **Audio (<i>recordings will not be reviewed without scripts</i>) <input type="checkbox"/> Other _____ | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| **To avoid unnecessary additional production costs due to re-work, it is strongly recommended that submitters seek WIRB pre-approval of scripts before producing the recordings. Any Board-required modifications to the material must be reflected in the final version of the recording. | | | |
| 59a. | Have any of these or similar recruitment materials been previously approved by WIRB for this protocol or other protocols? *If Yes, please attach a copy of the previously approved item(s). WIRB support staff will provide the Board with information about the previous Board review, so that the previous decision of the Board can be taken into account when the materials are reviewed. | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 60. | Are you using any written or verbal screening materials to screen subjects prior to enrollment in the research (such as telephone call scripts, written or web-based questionnaires or pre-screening forms)? *If Yes, please include them for review and describe the screening plan on the Screening Procedures Information Form provided at the end of this document (English documents only; see the translations question below for information about submitting documents in another language). WIRB reviews screening materials in the same fashion as consent documents. WIRB's requirements for screening scripts are listed at the bottom of the Screening Procedures Information form. | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 61. | Please describe the population from which you will recruit for this research by (provide the percentages of the ethnic populations): | | |
| 62. | Does the investigator have access to a population that will allow recruitment of the number of participants needed for this research? *If No, please explain: | Yes <input type="checkbox"/> | *No <input type="checkbox"/> |
| 63. | Please indicate the language(s) of the subjects the PI plans to enroll. <i>All the consent forms and other subject materials must be in a language easily understood by the subject.</i> Languages: _____ | | |
| 63a. | Indicate your consent form preference by checking one of the following: <input type="checkbox"/> Use enclosed (<i>if on disk, Microsoft Word compatible</i>). If you are using a sponsor's template consent form, please underline any changes you have made. <input type="checkbox"/> Request WIRB write consent form (<i>extra fee</i>) | N/A <input type="checkbox"/> | |

Initial Review Submission Form for International Sites

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VI. BILLING INFORMATION: Please tell us who should be billed for this review. (If this section is not completed, the PI will be billed.)

| | | | |
|------|--|------|---------------------------------|
| 68. | If you have listed someone other than yourself as the billing contact, please attach written verification from that person indicating he or she will pay for these services. If written verification is not received, the PI will be billed. | | |
| 68a. | Company Name: | | |
| 68b. | Attn.: | | |
| 68c. | Address: Street: City: Province or region (if applicable): Postal code (if applicable): Country: | | |
| 68d. | Phone: | Fax: | E-mail: |
| 68e. | Mail Stop/Cost Center: | | |
| 68f. | Purchase Order number (P.O.#), if applicable: | | N/A <input type="checkbox"/> |
| 68g. | Cost of the requested WIRB translation services will be paid by: (if applicable) | | N/A <input type="checkbox"/> |
| 68h. | Please describe any special billing instructions: | | N/A <input type="checkbox"/> |

VII. NAME OF PERSON COMPLETING THIS FORM: Please tell us who you are and how we can contact you if we have questions about this form.

| | | | |
|-----|---|--|--|
| 69. | <p>_____</p> <p>Printed or Typed Name of Person Completing This Form* Date Company & title</p> <p>_____</p> <p>Phone number Fax number E-mail address (optional)</p> <p><i>*Please note that the person named above will not receive copies of approval documents unless they are also listed in a question in this form that asks "How would the contact prefer to receive documents from WIRB?"</i></p> | | |
|-----|---|--|--|

Initial Review Submission Form for International Sites – *Additional Sites Listing*

Sponsor Protocol #: _____

Investigator Surname: _____

Submit additional copies of this page to list additional sites. List only sites at which subjects will be seen. Each site will be listed on the consent form.

| | | | |
|-----------|---|----------------------------------|---------------------------------|
| a. | Additional Site # 2: Name of Research Location: Physical Address: <i>(must match box 3 of submitted 1572, if applicable)</i> Street: City: Province or region (if applicable): Postal code (if applicable): Country: | N/A <input type="checkbox"/> | |
| b. | Site #2 Phone: | | |
| c. | What type of facility is this site? <input type="checkbox"/> Medical office <input type="checkbox"/> Hospital <input type="checkbox"/> University <input type="checkbox"/> Psychiatric Institution <input type="checkbox"/> Nursing home <input type="checkbox"/> Other <i>(specify):</i> _____ <input type="checkbox"/> Research Clinic <input type="checkbox"/> Dialysis Center | | |
| d. | Does this site have an obligation to use another IRB/ethics committee? *If Yes, WIRB will need a written statement from the other IRB/ethics committee acknowledging WIRB's review of this research. Please call Client Services for more information. | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| e. | What resources are available at this site to treat emergencies resulting from study-related procedures? <input type="checkbox"/> BLS trained personnel <input type="checkbox"/> ACLS trained personnel and crash cart <input type="checkbox"/> Emergency drugs and supplies to stabilize subject until emergency personnel arrive <input type="checkbox"/> Emergency response team within facility <input type="checkbox"/> Call emergency response number <input type="checkbox"/> Other <i>(specify):</i> _____ <input type="checkbox"/> N/A <i>(explain):</i> _____ and skip to question h. | | |
| f. | If this site is not a hospital, please name the medical facility to be used in an emergency: How far is this facility from the site? _____ | | |
| g. | Does the PI or a sub-investigator have staff privileges at the facility to be used in an emergency? *If No, attach a separate sheet of paper describing the following: <ul style="list-style-type: none"> • How subjects would be referred for hospitalization, • Name, address and telephone number of physician who has agreed to attend these patients, and • What measures would be taken to assure communication between the investigator and the attending physician | Yes <input type="checkbox"/> | *No <input type="checkbox"/> |
| h. | Approximate distance from main site: _____ If more than 50 miles (80 Kilometers) from the main site, please explain how the PI will provide adequate oversight of the distant sites: | | |

WIRB® Financial Interest Disclosure FORM

(For Sites Answering Yes to Question 10)

Drug or Device Name: _____ Sponsor Name: _____
Investigator Name: _____ Date: _____

Party with the Financial Interest:

(Please provide a separate form for each individual with a financial interest.)

Name: _____

Party's Position:

- Investigator Family Member (of PI or study staff)
 Sub-Investigator Institution (for example, Hospital, University, etc.)
 Other Research Staff Other Party: _____

Nature of Financial Interest: (check box and fill in information)

- Equity (stock, options, etc. - Does not include diversified mutual funds or similar instruments in which shareholder has no control over the equities held by the fund.):
- Publicly traded*
Number of Shares, etc.: _____ \$ value: _____
- Not publicly traded:*
Number of Shares You Hold, etc.: _____ \$ value: (estimate, if possible): _____
Approx. Total Number of Shares Issued: _____
- Recruitment incentives (bonus payments, etc.) \$ value: _____
 Consulting Fees during last 365 days (or indicate alternative period) \$ value: _____
 Speaking Fees during last 365 days (or indicate alternative period) \$ value: _____
 Gifts during last 365 days (or indicate alternative period) \$ value: _____
 Corporate Officer or Board of Directors \$ value: _____
 Other Employment Relationship \$ value: _____
 Trademarks \$ value: _____
 Copyrights \$ value: _____
 Licensing Agreements \$ value: _____
 Royalty Payments \$ value: _____
 Patent Holdings \$ value: _____
 Other (describe) _____ \$ value: _____

Comments:

WIRB® Recruitment Bonus Disclosure Form (For Sites Answering Yes to Question 11)

Sponsor Name: _____ Sponsor Protocol No.: _____
Investigator Name: _____ Date: _____

WIRB defines a recruitment bonus as an additional payment or incentive provided to the PI or staff dependent solely on a particular number of subjects being enrolled, or dependent on the speed at which subjects are enrolled. The term "payment or incentive" includes any items of value, such as direct payment, gift certificates, travel vouchers, physical items such as watches, etc.

Recipient of the Recruitment Bonus:

Name: _____

Position of recipient of bonus:

- Investigator
- Sub-Investigator
- Other Research Staff
- Institution (for example, Hospital, University, etc.)
- Other Party: _____

Description of Recruitment Bonus:

1. Who is providing the bonus? _____

2. Amount or form of recruitment bonus: \$ value: _____
(direct payment, gift certificates, travel vouchers, physical items such as watches, etc.)

3. Description of bonus, including conditions for payment of recruitment bonus:

(For example, PI receives \$XX for enrolling YY number of subjects within ZZ time period.)

Also, please attach any sponsor correspondence or materials describing the recruitment bonus program, or a copy of the budget for the research.

4. Please describe any additional costs that would be incurred by the site or the recipients of the bonus that would offset the value of the bonus:

(For example, the costs of additional advertising, costs of additional screening or testing, or staff time.)

Comments:

Screening Procedures Information Form (For Sites Answering Yes to Question 60)

WIRB®

| | |
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| 1. | <p>How is screening initiated?</p> <p><input type="checkbox"/> Incoming response to an ad or web site.</p> <p><input type="checkbox"/> Site or call center initiating a call to a patient whose name was obtained from a database or list.</p> <p>Please note: Provincial, state, or federal laws may prohibit unsolicited calls to people who have not given prior permission to be contacted.</p> |
| 2. | <p>Will you be using a call center?</p> <p><input type="checkbox"/> Yes.</p> <p><input type="checkbox"/> No. If no, go to question 9.</p> |

Questions about the call center's practices:

| | | | | |
|---|---|---|----------------------------------|--------------------------------|
| 3. | <p>How is information stored at the call center?</p> <p><input type="checkbox"/> In a database.</p> <p style="margin-left: 20px;">Describe the security measures in place: _____</p> <p style="margin-left: 20px;">_____</p> <p><input type="checkbox"/> On paper.</p> <p style="margin-left: 20px;">How and where is the paper stored? _____</p> <p style="margin-left: 20px;">_____</p> <p style="margin-left: 20px;">Who has access to the paper? _____</p> <p style="margin-left: 20px;">_____</p> | | | |
| 4. | How long does the call center store information? | | | |
| 5. | How does the call center destroy information at the end of the designated storage time? | | | |
| 6. | Describe how and when the call center destroys screening failure records: | | | |
| 7. | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%; padding: 5px;"> Does the call center sell or share the names of screened subjects to other entities? *If Yes, please explain: </td> <td style="width: 10%; text-align: center; vertical-align: middle;">*Yes <input type="checkbox"/></td> <td style="width: 10%; text-align: center; vertical-align: middle;">No <input type="checkbox"/></td> </tr> </table> | Does the call center sell or share the names of screened subjects to other entities? *If Yes, please explain: | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Does the call center sell or share the names of screened subjects to other entities? *If Yes, please explain: | *Yes <input type="checkbox"/> | No <input type="checkbox"/> | | |
| 8. | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%; padding: 5px;"> Does the call center forward subject information to the site? *If Yes, how is the subject information forwarded to the site? (for example, e-mail, fax) </td> <td style="width: 10%; text-align: center; vertical-align: middle;">*Yes <input type="checkbox"/></td> <td style="width: 10%; text-align: center; vertical-align: middle;">No <input type="checkbox"/></td> </tr> </table> | Does the call center forward subject information to the site? *If Yes, how is the subject information forwarded to the site? (for example, e-mail, fax) | *Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Does the call center forward subject information to the site? *If Yes, how is the subject information forwarded to the site? (for example, e-mail, fax) | *Yes <input type="checkbox"/> | No <input type="checkbox"/> | | |

Questions about the site's practices:

| | |
|----|---|
| 9. | <p>How is information stored at the site?</p> <p><input type="checkbox"/> In a database.</p> <p style="margin-left: 20px;">Describe the security measures in place: _____</p> <p><input type="checkbox"/> On paper.</p> <p style="margin-left: 20px;">How and where is the paper stored? _____</p> <p style="margin-left: 20px;">Who has access to the paper? _____</p> |
|----|---|

WIRB Screening Procedures Information Form (cont'd)

| | | | | |
|-----|---|----------------------------------|---------------------------------|--------------------------------|
| 10. | How long is information stored at the site? | | | |
| 11. | How does the site destroy information at the end of the designated storage time? | | | |
| 12. | Does the site keep screening failure records with the other study records? *If No, please describe how and when they will be destroyed: | Yes <input type="checkbox"/> | *No <input type="checkbox"/> | |
| 13. | Does the site sell or share the names of screened subjects to other entities? *If Yes, please explain: | *Yes <input type="checkbox"/> | No <input type="checkbox"/> | |
| 14. | If the site receives subject information faxed from a call center, is the fax machine at the site accessible only to authorized study personnel? Comments: | Yes <input type="checkbox"/> | No <input type="checkbox"/> | NA <input type="checkbox"/> |

WIRB Screening Requirements:

Introductory Statement:

- The script must include an introductory statement that informs the subject of the purpose of the questions and that they do not have to answer any questions they do not want to answer.
- The script must not describe the type of questions that will be asked as "confidential;" i.e., rather than saying "we would like to ask you some *confidential* questions," say "we would like to ask you some questions." It is acceptable to say "personal questions" or "sensitive questions." The purpose of this policy is to prevent any possible misunderstanding that the answers will be held in complete confidence.
- When appropriate, the script must include an introductory statement warning the subjects of the sensitive nature of the questions that might make the subject uncomfortable, and preferably include an example (for instance, "We are going to ask you about drug or alcohol use.") This will generally be limited to questions about mental illness, substance abuse, and sexual abuse. For these types of screening scripts, it is preferable to not collect any identifying information until after the questions are asked (i.e., collect the name and other identifying information at the end of the conversation and the form).

Here is a sample introductory statement:

[Thank you for calling] (or) [We are returning your call] about a research study we will be doing. The purpose of the study is [briefly describe study - for example, ". . . to evaluate the safety and effectiveness of an investigational drug for arthritis"]. Participation in this study would last about [number of days, weeks, etc.] and (if applicable) would require up to [number] of visits to our office.

To see if you might qualify for this study, I need to ask you some questions about your health history and present condition. Some of these questions may be sensitive, such as questions about [give examples - for example, drug use, birth control, mental health, sexual activity, etc.] You do not have to answer any questions you do not want to answer. You may stop this interview at any time. If you do not qualify for this study, the information you give me will be [for example, "destroyed immediately" or "stored (where and for how long)"]. Do I have your permission to proceed? "

Body of Screening Form

- The Board expects to see the actual questions that will be asked, not just a general statement such as "inclusion/exclusion criteria addressed."

Closing Statement

- The script must include a closing statement informing the subject of whether or not they have met the preliminary screening requirements.
- The script must address in a closing statement whether the information received from the subject will be destroyed immediately, or whether it will be stored, and if so for how long and where.
- If the site would like to keep information for future contact for new studies, this must be described to the subject as well, and the subject must have an opportunity to decline.

Additional Issues

- The screening script must be in language understandable by lay people. If complicated medical terms must be included in the screening script, please provide WIRB with an explanation of how they will be explained to the subjects.
- WIRB realizes that the script may not be followed verbatim, as subjects may ask additional questions or stray from the topic. This is acceptable, but WIRB expects that the interviewer will keep as closely as possible to the spirit and letter of the script.
- It is useful to WIRB if the investigator informs WIRB of the use of the recruitment screen; for example, if it is going to be used with subjects calling in from advertisements, for calling patients listed in a database, or for conducting cold calls.