

WIRB®

WESTERN INSTITUTIONAL REVIEW BOARD®
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(360) 252-2500 • 1-800-562-4789 • Fax (360) 252-2498
www.wirb.com • clientservices@wirb.com

OHRP/FDA Parent Organization number: IORG0000432 • IRB registration number: IRB00000533



WIRB INITIAL REVIEW SUBMISSION REQUIREMENTS

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 must include one copy of the following:

- **Current version of WIRB initial review submission form.** You may utilize WIRB's new online "smart form" feature to complete this form (click on the yellow "WIRBNet Login" button at www.wirb.com), or you may download a Word version or PDF from the Download Forms page to complete and forward to us.
- **Protocol*** (WIRB can assist during the planning stages of a multi-center study by **pre-reviewing** the protocol and subject materials, including the consent form. Please use the WIRB form "**Initial Review Submission Form for Sponsors and CROs**" available on the download forms page of www.wirb.com.)
- **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)
- **Qualified Investigator Undertaking Form** (Canadian sites)
- **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.

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Initial Review Submission Form

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 #: _____

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); for Canadian investigators: Part C Division 5 of the <i>Food and Drug Regulations</i> , Part 4 of the <i>Natural Health Products Regulations</i> (if applicable), <i>Medical Devices Regulations</i> (if applicable)]			
1.	PI Name:	Gender: <input type="checkbox"/> M <input type="checkbox"/> F	
1a.	PI Company Name:		
1b.	PI Mailing Address: (street, city, state/province, postal code, 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:		Gender: <input type="checkbox"/> M <input type="checkbox"/> F
2a.	Study Coordinator Phone: ()	Study Coordinator Fax: ()	Study Coordinator E-mail:

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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 #: State/province: Expiration Date:	N/A <input type="checkbox"/>	
8b.	If this PI will conduct research involving an investigational drug in the state of Massachusetts, provide a copy of the Massachusetts Research Registration under which the research will be conducted. Registration number: If a registration has not been obtained, forward a copy as soon as it is available.	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; • Canadian Qualified Investigator Undertaking Form; • 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.		

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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"/>
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 (explain): _____		
13.	For Canadian sites , the Canadian Tri-Council Policy Statement, Article 7.3, requires that the REB review the clinical trial budget. Please attach the clinical trial budget.	Attached <input type="checkbox"/>	N/A <input type="checkbox"/>
14.	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)		
15.	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)		
16.	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?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
16a.	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"/> Tri Council Policy Statement online training (for Canadian sites). This training is strongly recommended. <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: (specify) _____ 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.		

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17.	Will a Site Management Organization (SMO) or similar be involved in this research? If No, proceed to question 18.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
17a.	SMO Name:		
17b.	SMO Address: (street, city, state/province, postal code, country)		
17c.	SMO Contact Name:	Gender: <input type="checkbox"/> M <input type="checkbox"/> F	
17d.	SMO Contact Phone: () ()	SMO Contact Fax: () ()	SMO Contact E-mail:
17e.	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.

18.	Protocol Number and Version Date:		
19.	Protocol title:		
20.	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"/>
21.	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"/>
22.	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"/>
23.	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"/>	

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24.	Has another IRB 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 correspondence.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
25.	Is this study being transferred to WIRB from another IRB? *If Yes, please fill out the IRB Transfer form posted at www.wirb.com .	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
26.	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"/>
27.	Is this research federally funded entirely or in part? If No, proceed to question 28. (There are additional regulatory requirements for investigators seeking approval of federally funded research. A summary of the requirements is available at http://www.wirb.com/content/wirb_services_irbservices_fed.aspx .)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
27a.	What federal agency(ies) is funding this research?	N/A <input type="checkbox"/>	
27b.	Provide a copy of the complete grant (if applicable).	N/A <input type="checkbox"/>	
27c.	If this grant funds multiple protocols, please list the protocols previously reviewed by WIRB.	N/A <input type="checkbox"/>	
27d.	Provide the federal contract (if applicable).	N/A <input type="checkbox"/>	
28.	Does this research involve a Drug, Biologic or Dietary Supplement? If No, proceed to question 29.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
28a.	Provide the Investigational New Drug (IND) number assigned by the FDA and/or the Health Canada Clinical Trial Control Number (Canadian sites): (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, a copy of the FDA letter indicating an IND is not required, the investigator or sponsor's explanation for why an IND is not necessary, etc.)	N/A <input type="checkbox"/>	
28b.	Attach documentation from the sponsor or FDA verifying the IND number and/or the Health Canada No Objection Letter if available (Canadian sites) 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"/> The Health Canada No Objection Letter is not available. A copy will be forwarded to WIRB when available. <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"/>	
28c.	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"/>	

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29.	Does this research involve an Investigational Device? *If Yes, proceed to question 29a.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
29a.	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"/>
30.	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 31.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
30a.	Has this been submitted to the Recombinant DNA Advisory Committee (RAC)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
30b.	If available, attach the Response to Appendix M of the National Institutes of Health (NIH) Guidelines.	N/A <input type="checkbox"/>	
30c.	If available, attach copies of the RAC correspondence regarding the protocol.	N/A <input type="checkbox"/>	
30d.	Has there been an Institutional Biosafety Committee (IBC) review? *If Yes, please attach the IBC recommendations.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
31.	Sponsor Name:		
31a.	Sponsor Contact Name:	Gender: <input type="checkbox"/> M <input type="checkbox"/> F	
31b.	Sponsor Contact Address: (street, city, state/province, postal code, country)		
31c.	Sponsor Contact Phone: () ()	Sponsor Contact Fax: () ()	Sponsor Contact E-mail:
31d.	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		
31e.	Medical Monitor Name: (first and last name, plus degree if known)	Gender: <input type="checkbox"/> M <input type="checkbox"/> F	
31f.	Medical Monitor Phone: () ()	Medical Monitor Fax: () ()	Medical Monitor E-mail:
32.	Is a Contract Research Organization (CRO) involved in this research? If No, proceed to question 33.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
32a.	CRO Name:		

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32b.	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"/>
32c.	CRO Address: (street, city, state/province, postal code, country)			
32d.	CRO Contact Name:	Gender: <input type="checkbox"/> M <input type="checkbox"/> F		
32e.	CRO Contact Phone: ()	CRO Contact Fax: ()	CRO Contact E-mail:	
32f.	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 or Canadian Qualified Investigator Undertaking form, 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 (or QIU) 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.

33.	<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: Physical Address: (street, city, state/province, postal code, country) <i>(must match box 3 of submitted 1572 or part 3 of Canadian QIU form, if applicable)</i></p>			
33a.	Site #1 Phone: ()			
33b.	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 (specify): _____ <input type="checkbox"/> Research Clinic <input type="checkbox"/> Dialysis Center			
33c.	Does this site have an obligation to use another IRB? *If Yes, <ul style="list-style-type: none"> • please provide the name and contact for the IRB below; and • WIRB will need a written statement from the other IRB acknowledging WIRB's review of this research. Please call Client Services for more information. IRB Name: _____ IRB Phone Number: _____ IRB E-mail Address (if known): _____	*Yes <input type="checkbox"/>	No <input type="checkbox"/>	

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33d.	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 911 <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> N/A; explain: _____ and skip to question 33g.		
33e.	If this site is not a hospital, please name the medical facility to be used in an emergency: How far is this medical facility from the site? _____		
33f.	Does the PI or a sub-investigator have staff privileges at the facility to be used in an emergency? *If No, you must 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"/>

33g.	For each additional site, please copy, complete and attach the Additional Site Listing form at the end of this document.	N/A <input type="checkbox"/>
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34.	What is the local attitude toward human subject research? <input type="checkbox"/> Positive <input type="checkbox"/> Negative If other than positive, please explain:
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35.	Have there been any recent changes to laws governing medical research in your state/province? If yes, please provide whatever information you have.	Yes <input type="checkbox"/>	No <input type="checkbox"/>	unknown <input type="checkbox"/>
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36.	<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> <input type="checkbox"/> Use of drapes or other barriers for subjects who are required to disrobe. <input type="checkbox"/> Research intervention is conducted in a private room. <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. <input type="checkbox"/> Other (specify): _____ _____ _____
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IV. RECRUITMENT, CONSENT & SUBJECT PAYMENT INFORMATION: Please provide information about how subjects will be recruited, the consent form subjects will be asked to sign, and what type of payment subjects will receive.

40.	<p>Do you intend to enroll any subjects from the following "vulnerable" categories? *If Yes, please list all vulnerable subject groups, even those clearly identified in the protocol inclusion criteria.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Prisoners <input type="checkbox"/> Minors <input type="checkbox"/> Poor/uninsured <input type="checkbox"/> Institutionalized <input type="checkbox"/> Limited or non-readers <input type="checkbox"/> Wards of the state (e.g., foster children) <input type="checkbox"/> Pregnant women (if yes, you must complete question 40a) <input type="checkbox"/> Nursing home residents recruited in the nursing home <input type="checkbox"/> Students of PI or study staff <input type="checkbox"/> Students to be recruited in their educational setting, i.e., in class or at school <input type="checkbox"/> Employees directly supervised by PI or sub-investigator <input type="checkbox"/> Employees of research site or sponsor <input type="checkbox"/> Military personnel to be recruited by military personnel <input type="checkbox"/> Cognitively impaired (if yes, you must answer question 40b) <input type="checkbox"/> Adult subjects who cannot consent for themselves; i.e., requiring consent by a legally authorized representative (if yes, you must answer questions 41a-c) <input type="checkbox"/> Others vulnerable to coercion (specify): _____ 	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
40a.	<p>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 60):</p> <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"/>	
40b.	<p>If some or all subjects will be cognitively impaired, describe how capacity for consent will be determined:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Capacity assessment using the following method or instruments: _____ <input type="checkbox"/> Other (specify): _____ 	N/A <input type="checkbox"/>	
41.	<p>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.)</p> <p>*If Yes, you must answer questions 41a, 41b, and 41c below.</p> <p>New Jersey sites, if Yes, also complete and submit the supplemental form "New Jersey Requirements for Inclusion of Decisionally Impaired Subjects (New Jersey Statute 26:14-2)" available on the Download Forms page of www.wirb.com.</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>

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41a.	How do you determine which individuals meet the criteria for being a Legally Authorized Representative (LAR) under your state/provincial and local law? (WIRB can provide a copy of the relevant statutes for your state upon request. Advice from your legal counsel is strongly recommended to determine local or state law requirements.) _____ _____	N/A <input type="checkbox"/>	
41b.	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"/>	
41c.	If your state/provincial/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"/>
42.	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): _____		
43.	Please describe the circumstances and location of the consent process: (check all that apply) <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). <input type="checkbox"/> In a private room <input type="checkbox"/> In a waiting room <input type="checkbox"/> In an open ward <input type="checkbox"/> In a group setting <input type="checkbox"/> In a group setting with follow up in a private room. <input type="checkbox"/> In emergency situations . The process is as follows (explain here or attach a separate sheet): _____ _____ _____ <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): _____ _____ _____ <input type="checkbox"/> Other (specify): _____ _____ _____		

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44.	How will you be sure there is sufficient opportunity for the subject to consider whether to consent? (check all that apply) <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.) <input type="checkbox"/> Subjects will be allowed a waiting period of at least _____ hours to consider their decision. <input type="checkbox"/> Other (specify): _____
45.	Describe steps taken to minimize the possibility of coercion or undue influence: (check all that apply) <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 (e.g., there will not be over-emphasis of benefits or under-emphasis of risks). <input type="checkbox"/> Other (specify): _____
46.	Mark one of the following regarding waiver of rights during the consent process: <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. <input type="checkbox"/> Other (specify): _____

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47.	<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 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-bottom: 1px solid black; margin-bottom: 5px;"></div> <div style="width: 45%; border-bottom: 1px solid black; margin-bottom: 5px;"></div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div style="width: 45%; border-bottom: 1px solid red; margin-bottom: 5px;"></div> <div style="width: 45%; border-bottom: 1px solid red; margin-bottom: 5px;"></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): _____
48.	<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 (e.g., 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>
49.	<p>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.)</p> <ul style="list-style-type: none"> <input type="checkbox"/> I confirm <input type="checkbox"/> Other (explain) _____

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50.	<p>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 _____</p> <p style="font-size: small;">**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.</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
50a.	<p>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.</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
51.	<p>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.</p> <p style="font-size: small;">Please send this form even if the materials were developed and submitted to WIRB by the sponsor. WIRB's requirements for screening scripts are listed at the end of the Screening Procedures Information form.</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
52.	<p>Please describe the population from which you will recruit for this research: If your site is in the U.S. or Canada: (please round to nearest whole number)</p> <p>Race: (should add up to 100%) _____ % Black or African-American _____ % Asian _____ % Native Hawaiian or other Pacific Islander _____ % White _____ % American Indian or Alaska Native/First Nations _____ % Other: _____</p> <p>Ethnicity: (should add up to 100%) _____ % Hispanic or Latino _____ % Not Hispanic or Latino</p> <p>If your site is located outside the U.S. or Canada: Please indicate the names and percentages of the applicable ethnic populations.</p>		
53.	<p>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:</p>	Yes <input type="checkbox"/>	*No <input type="checkbox"/>

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54.	<p>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, and all translations must be approved by WIRB. If you plan to enroll only English-speaking subjects, please enter "English" below.</i></p> <p><input type="checkbox"/> Languages: _____</p> <p>Or</p> <p><input type="checkbox"/> The protocol prohibits enrollment of non-English speaking subjects.</p>			
55.	<p>If you are enrolling non-English speaking subjects, please explain the plans for translation:</p> <p><input type="checkbox"/> After I receive the WIRB-approved consent form and subject materials, I (or the sponsor) will hire a translator to translate the approved documents. I will then submit a certification of translation and materials to WIRB for verification (administrative fee applies).</p> <p>All translations must be accompanied by a certification of translation. Contact the WIRB Translations Department for requirements.</p> <p><input type="checkbox"/> I would like WIRB to provide translation of the consent forms and/or other subject materials.* (translation fee applies)</p> <p>*If you would like WIRB to translate the documents, please list each item you would like translated and indicate the languages requested:</p> <p>Items: _____</p> <p>Languages: _____</p>	N/A		
55a.	<p>If you are enrolling non-English speaking subjects, you must have plans for 1) conducting the consent discussion in the language understandable to the subject, and for 2) ongoing communication with the subject throughout the research and in case of emergency. (check all that apply)</p> <p><input type="checkbox"/> At least one member of the research team is fluent in the language that will be used for communication, and that research staff member(s) will be available during emergencies.</p> <p><input type="checkbox"/> The research team has 24-hour access to a translation service with sufficient medical expertise to discuss the research in this study.</p> <p><input type="checkbox"/> Other (explain): _____</p> <p><i>Note: This requirement is in addition to the requirement to use a translated consent form. WIRB does not allow ad hoc oral translation into another language during the consent process.</i></p>	N/A		
56.	<p>For investigators participating in multi-center studies, it is likely a consent form for this protocol has already been approved by WIRB. If available, would you like to use it? WIRB will incorporate any institutionally required language and your site-specific contact information, payment information, locations, etc. from this submission form into the previously approved consent. Selecting "yes" can significantly reduce the processing time and you will receive your documents more quickly. To verify that a previously approved consent form is available for this protocol, please call Client Services at 1-800-562-4789.</p> <p>If answering Yes, proceed to question 57, and you do not need to submit a consent form with your review materials.</p>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

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56a.	<p>If you prefer not to use the previously approved WIRB consent form for this protocol or this is not a multi-center study, indicate your consent form preference by checking one of the following:</p> <p><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.</p> <p><input type="checkbox"/> Request WIRB write consent form (<i>extra fee</i>)</p>	N/A <input type="checkbox"/>
57.	<p>Contact information to be listed in the Consent Form: Contact name and phone number for questions about the study:</p> <p>Name _____ Phone number(s):</p> <p>(____) _____ <input type="checkbox"/> Office Hours <input type="checkbox"/> 24 hours <input type="checkbox"/> Pager (check all that apply)</p> <p>(____) _____ <input type="checkbox"/> Office Hours <input type="checkbox"/> 24 hours <input type="checkbox"/> Pager (check all that apply)</p> <p>Contact name and phone number for use in the event of research-related injury:</p> <p>Name _____ Phone number(s):</p> <p>(____) _____ <input type="checkbox"/> Office Hours <input type="checkbox"/> 24 hours <input type="checkbox"/> Pager (check all that apply)</p> <p>(____) _____ <input type="checkbox"/> Office Hours <input type="checkbox"/> 24 hours <input type="checkbox"/> Pager (check all that apply)</p> <p>Your review may be delayed if we need to obtain clarification from you because the contact information listed above differs from the contact information listed in the consent form(s) you submit.</p> <p>If the contact information listed above changes, you will need to notify WIRB (a consent form modification fee will apply). Please request the necessary changes using the Change In Research and Subject Recruitment (Ads) Submission Form available at www.wirb.com.</p> <p>NOTE: The Board takes very seriously a subject's ability to successfully contact a study staff member. If WIRB staff or subjects report being unable to contact a study staff member (as indicated above), the Board may take action to restrict the research at the site.</p>	N/A <input type="checkbox"/> (sites requesting waiver of consent only)
58.	<p>WIRB routinely displays the name and contact information of the <u>Principal Investigator</u> and, if applicable, the <u>Co-Principal Investigator</u> on the first page of the consent form (unlike sub-investigators, Co-Principal Investigators share total responsibility for the conduct of the study). WIRB does not routinely display the names or contact information of sub-investigators or study coordinators unless asked to do so. If you would like the names of any sub-investigators or study coordinators to appear on the first page of the consent form, please insert the names below as you would like them to appear.</p> <p>SUB- INVESTIGATOR(S): [first name last name, degree] [Phone number (optional)]</p> <p>STUDY COORDINATOR(S): [first name last name, degree] [Phone number (optional)]</p> <p>If the information changes, you must notify WIRB (a consent form modification fee will apply). Please request the necessary changes using the Change In Research and Subject Recruitment (Ads) Submission Form available at www.wirb.com.</p>	N/A <input type="checkbox"/>

Initial Review Submission Form

WIRB[®]

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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.)

61.	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.		
61a.	Company Name:		
61b.	Attn.:		
61c.	Address: (street, city, state/province, postal code, country)		
61d.	Phone: ()	Fax: ()	E-mail:
61e.	Mail Stop/Cost Center:		
61f.	Purchase Order number (P.O.#), if applicable:		N/A <input type="checkbox"/>
61g.	Cost of the requested WIRB translation services will be paid by: (if applicable)		N/A <input type="checkbox"/>
61h.	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.

62.	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border-bottom: 1px solid black; width: 45%;"></td> <td style="border-bottom: 1px solid black; width: 20%;"></td> <td style="border-bottom: 1px solid black; width: 35%;"></td> </tr> <tr> <td>Printed or Typed Name of Person Completing This Form*</td> <td>Date</td> <td>Company & title</td> </tr> <tr> <td style="border-bottom: 1px solid black;">()</td> <td style="border-bottom: 1px solid black;">()</td> <td style="border-bottom: 1px solid black;"></td> </tr> <tr> <td>Phone number</td> <td>Fax number</td> <td>E-mail address (optional)</td> </tr> </table> <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>						Printed or Typed Name of Person Completing This Form*	Date	Company & title	()	()		Phone number	Fax number	E-mail address (optional)
Printed or Typed Name of Person Completing This Form*	Date	Company & title													
()	()														
Phone number	Fax number	E-mail address (optional)													

WIRB® Financial Interest Disclosure FORM

(For Sites Answering Yes to Question 10)

Sponsor Name: _____ Sponsor Protocol No.: _____

Investigator Name: _____ Date: _____

Party with the Financial Interest:

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

Name: _____

Party's Position:

- | | |
|---|--|
| <input type="checkbox"/> Investigator | <input type="checkbox"/> Immediate Family Member of PI or study staff (spouse or dependent children) |
| <input type="checkbox"/> Sub-Investigator | <input type="checkbox"/> Institution (e.g., Hospital, University, etc.) |
| <input type="checkbox"/> Other Research Staff | <input type="checkbox"/> 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: _____
- | | |
|--|-----------------|
| <input type="checkbox"/> Recruitment incentives (bonus payments, etc.) | \$ value: _____ |
| <input type="checkbox"/> Consulting Fees during last 365 days (or indicate alternative period) | \$ value: _____ |
| <input type="checkbox"/> Speaking Fees during last 365 days (or indicate alternative period) | \$ value: _____ |
| <input type="checkbox"/> Gifts during last 365 days (or indicate alternative period) | \$ value: _____ |
| <input type="checkbox"/> Corporate Officer or Board of Directors | \$ value: _____ |
| <input type="checkbox"/> Other Employment Relationship | \$ value: _____ |
| <input type="checkbox"/> Trademarks | \$ value: _____ |
| <input type="checkbox"/> Copyrights | \$ value: _____ |
| <input type="checkbox"/> Licensing Agreements | \$ value: _____ |
| <input type="checkbox"/> Royalty Payments | \$ value: _____ |
| <input type="checkbox"/> Patent Holdings | \$ value: _____ |
| <input type="checkbox"/> 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 (e.g., 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 51)

WIRB®

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 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;">_____</p> <p style="margin-left: 20px;">Who has access to the paper? _____</p> <p style="margin-left: 20px;">_____</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.	<p>Does the call center sell or share the names of screened subjects to other entities?</p> <p>*If Yes, please explain:</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
8.	<p>Does the call center forward subject information to the site?</p> <p>*If Yes, how is the subject information forwarded to the site? (for example, e-mail, fax)</p> <p>_____</p>	*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;">_____</p> <p style="margin-left: 20px;">Who has access to the paper? _____</p> <p style="margin-left: 20px;">_____</p>
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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:

(If you plan to screen Canadian citizens, please call Client Services for more information about Canadian 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 - e.g., “. . . 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 - e.g., 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 [e.g., “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; e.g., 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.