WIRB®
WESTERN INSTITUTIONAL REVIEW BOARD®
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www.wirb.com • clientservices@wirb.com
OHRP/FDA Parent Organization number: IORG0000432 • IRB registration number: IRB00000533

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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.

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.)
- **Consent Form** under some circumstances (see question #2). Please submit consent forms as Microsoft Word compatible files.
- **Current professional license** for Principal Investigator, showing the expiration date*
- **Curriculum Vitae** (CV) for Principal Investigator and each Sub-Investigator*
- **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*
- 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 recommendations (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.

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

If a DEVICE study, provide device manual (also called "Instructions for Use") 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 and the basis for that determination;* OR
- **Documentation of why the investigation is exempt** from the IDE requirements under 21CFR 812.2(c) (such as the PMA approval letter/number or 510(k) clearance letter/number) or otherwise exempt.*

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

Instructions for completing this form:

- Effective January 1, 2011, WIRB does not accept handwritten versions of this form. You must 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.
- The information provided in this submission form (addresses, phone numbers, contact names, payment information, etc.) will be used to produce your final regulatory documents and consent forms. Please note that 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.

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Initial Review Submission Form

1.	Sponsor Name _____ Sponsor Protocol Number: _____
2.	If this is a multi-center protocol, it is likely that the protocol has already been reviewed by WIRB. If so, we recommend using the WIRB form "Investigator Submission Form for Multi-Center Protocols" instead of this submission form, as it is a shorter form with fewer questions. To find out if WIRB has already reviewed this protocol, you may contact WIRB's Client Services at (800) 562-4789 or clientservices@wirb.com. Also, if WIRB has already approved the protocol, generally a consent form has also already been approved by the Board and approved by the sponsor. *(Please note that if you would like to preview the consent form currently approved by WIRB before making a selection below, we are happy to provide you with a preview copy whenever possible.)* Please indicate your consent form preference below. *More information about these choices is available here: http://www.wirb.com/content/foot_wirb_faq.aspx#36*: ☐ If one is available, I would like to use the previously approved WIRB consent form. By choosing this option, the processing time will be greatly reduced. WIRB will automatically incorporate your site-specific contact information, payment information, and locations from this submission form into the previously approved consent form. For investigators from affiliated institutions, required institutional language will also be automatically incorporated. (When this option is selected, a consent form does not need to be submitted with the review materials. If you would like to verify that a previously approved consent form is available for this protocol, please call Client Services at 1-800-562-4789.) For more information about this option, click here. ☐ I would like the Board to consider text that differs from the currently approved version of the consent form. Please note: if you select this option, you must provide the text you would like the board to consider by incorporating the revised text into the current version approved by WIRB (using Word's track changes feature or otherwise marking your additions clearly). Contact us to request a copy of the current WIRB approved consent form and provide your changes on that version. The *sponsor's template* with your changes marked will not be accepted. For more information about this option, click here. ☐ This is a new protocol or it is my understanding that a previously approved consent form is not available; therefore, I am submitting a copy of the consent form(s) I would like to use as Microsoft Word compatible file(s). *(If the consent form submitted is based on the sponsor's template, please clearly mark any changes to it you have made.)* For more information about this option, click here. ☐ I would like WIRB to write the consent form *(extra fee).* For more information about this option, click here. ☐ I am not requesting approval of a consent form for the following reason: ☐ I am requesting approval of a waiver of consent. [If your proposed research is subject to HIPAA regulations (you are at a "covered entity" and the research involves collection or use of identifiable health information), you will need to complete and submit the WIRB form "Request for Full Waiver of Authorization under HIPAA"], ☐ This is on-label use of a Humanitarian Use Device (HUD), ☐ This site is an administrative site where subjects will not be seen. ☐ Other: (specify) _____ For more information about this option, click here.

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 *Food and Drug Regulations*, Part 4 of the *Natural Health Products Regulations* (if applicable), *Medical Devices Regulations* (if applicable)]		
3.	PI Name:	Gender: ☐ M ☐ F	
3a.	PI Company Name:		
3b.	PI Mailing Address: (street, city, state/province, postal code, country)		
3c.	PI Phone: ( )	PI E-mail:	
3d.	PI Degree(s):	PI Specialty(ies):	
3e.	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 ☐
4.	Study Coordinator: (designated contact for this research other than the PI)		N/A ☐
4a	Gender: ☐ M ☐ F		
4b.	Study Coordinator Company Name:		
4c.	Study Coordinator Phone: ( )	Study Coordinator E-mail:	
4d.	Does the study coordinator need to receive a copy of the regulatory documents in addition to the copy sent to the PI? (study documents will be e-mailed) 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.	Yes ☐	No ☐

5.	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 5a below.	*Yes ☐	No ☐
5a.	CRRF contact name and mailing address: (first and last name, location name, street, city, state/province, postal code, country) Name: Location Name: Address: Phone: (_____) _____ E-mail: _____ *Note: The information collected above is used solely for the delivery of CRRFs; they will not receive other study documents unless they are also listed in this form as the study coordinator, SMO contact, etc.*		
6.	Has the PI ever received an FDA "Warning Letter" or Health Canada Inspection Report that has **not** been previously submitted to WIRB? ☐ Yes (You must attach all relevant correspondence and reports.) ☐ No (The PI has not received one, or the PI has, but it has been previously reported to WIRB.)		
7.	Has the PI ever had any research at their site suspended or terminated by an IRB *other than WIRB*? *If Yes, complete question 7a.	*Yes ☐	No ☐
7a.	Has the instance of suspended and/or terminated research referenced above been reported to WIRB prior to this submission? ☐ Yes ☐ No (You must attach information about the incident and its outcome.)		
8.	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 8a.	*Yes ☐	No ☐
8a.	Has the conviction and/or discipline referenced above been reported to WIRB prior to this submission? ☐ Yes ☐ No (You must attach information about the incident and its outcome.)		
9.	Have any of the *sub-investigators or study staff* 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 9a.	*Yes ☐	No ☐
9a.	Has the *sub-investigator's or study staff* conviction and/or discipline referenced above been reported to WIRB prior to this submission? ☐ Yes. Name of sub-investigator or staff member: ☐ No (You must attach information about the incident and its outcome.)		

10.	*Licensing Information: Please fill in the information requested below and attach legible copies of all pertinent current licenses and registrations (if not on file at WIRB). If necessary, please enlarge the copy of the license for legibility.*	
10a.	Medical or Professional License #: State/province: Expiration Date:	N/A ☐
10b.	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 ☐
11.	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 *Financial Interest Disclosure Form* provided at the end of this submission form. ☐ 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) ☐ Has a financial interest in the research with value that cannot be readily determined (for example, stock that is not publicly traded); ☐ 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; ☐ Has a financial interest in the research with value that exceeds 5% ownership; ☐ Has received or will receive compensation with value that may be affected by the outcome of the study; ☐ Has a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement; ☐ 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; ☐ Is an employee of the agency or company sponsoring the research; ☐ Is on the board of directors of the sponsor; ☐ Has a financial interest that requires disclosure to the sponsor or funding source; or ☐ Has any other financial interest that the investigator believes may interfere with his or her ability to protect subjects. ☐ Is affiliated with an institution with a lower conflict of interest threshold than the amounts referenced above. ☐ No, none of the above are true.	
12.	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 ☐ No ☐
13.	Please confirm that if any proposals are made to enact *recruitment bonuses* 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). ☐ I confirm ☐ Other (explain): _____	
14.	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 ☐ N/A ☐

15.	For this 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)		
16.	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)		
17.	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 ☐	No ☐
17a.	Indicate what type(s) of training were completed: (mark at least one, and all that apply) ☐ NIH online tutorial "Protecting Human Research Participants" ☐ NCI Human Participant Protections Education for Research Teams ☐ Tri Council Policy Statement online training (for Canadian sites). This training is strongly recommended. ☐ Collaborative Institutional Training Initiative (CITI) ☐ WIRB-sponsored Investigator or GCP course ☐ Academic/medical center's institutional human subject protection training requirements satisfied ☐ N/A – this submission is for one of the following: ☐ A Treatment IND or Treatment IDE ☐ Non-research use of a Humanitarian Use Device ☐ 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.		
18.	Will a Site Management Organization (SMO) or similar be involved in this research? If No, proceed to question 19.	Yes ☐	No ☐
18a.	SMO Name:		
18b.	SMO Address: (street, city, state/province, postal code, country)		
18c.	SMO Contact Name:	Gender: ☐ M ☐ F	
18d.	SMO Contact Phone: ( )	SMO Contact E-mail:	

II.	SPONSOR & PROTOCOL INFORMATION: Please tell us about the research to be conducted.		
19.	Protocol Number and Version Date:		
20.	Protocol title:		
21.	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 ☐	No ☐
22.	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 ☐	No ☐
23.	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 ☐	No ☐
24.	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 ☐
25.	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 ☐	No ☐
26.	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 ☐	No ☐
27.	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 ☐	No ☐
28.	Is this research federally funded entirely or in part? If No, proceed to question 29. (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 ☐	No ☐
28a.	What federal agency(ies) is funding this research?		N/A ☐

28b.	Provide a copy of the complete grant or contract if you/your institution are the awardee of the grant.		N/A ☐
28c.	If this grant funds multiple protocols, please list the protocols previously reviewed by WIRB.		N/A ☐
29.	Does this research involve a Drug, Biologic or Dietary Supplement? If No, proceed to question 30.	Yes ☐	No ☐
29a.	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 ☐
29b.	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 and indicate one or more of the following: ☐ FDA letter is attached. ☐ Sponsor letter is attached. ☐ IND number is in protocol or other sponsor-generated document. ☐ Other (specify): _____ ☐ The Health Canada No Objection Letter is not available. A copy will be forwarded to WIRB when available. ☐ Already on file with WIRB (Copy not necessary if already on file with WIRB. Contact WIRB's Client Services for information.)		N/A ☐
29c.	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 ☐
30.	Is the purpose of this study to determine the safety or effectiveness of a device? *If Yes, proceed to question 30a.	*Yes ☐	No ☐
30a.	You must provide one of the following: • 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 and the basis for that determination, or • Documentation explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2(c) (such as the PMA approval letter/number or 510(k) clearance letter/number) or otherwise exempt.		N/A ☐
31.	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 32.	Yes ☐	No ☐
31a.	Has this been submitted to the Recombinant DNA Advisory Committee (RAC)?	Yes ☐	No ☐
31b.	If available, attach the Response to Appendix M of the National Institutes of Health (NIH) Guidelines.		N/A ☐
31c.	If available, attach copies of the RAC correspondence regarding the protocol.		N/A ☐

31d.	Has there been an Institutional Biosafety Committee (IBC) review? *If Yes, please attach the IBC recommendations.	*Yes ☐	No ☐
32.	Sponsor Name:		
32a.	Sponsor Contact Name:	Gender: ☐ M ☐ F	
32b.	Sponsor Contact Address: (street, city, state/province, postal code, country)		
32c.	Sponsor Contact Phone: ( )	Sponsor Contact E-mail:	
32d.	Medical Monitor Name: (first and last name, plus degree if known)	Gender: ☐ M ☐ F	
32e.	Medical Monitor Phone: ( )	Medical Monitor Fax: ( )	Medical Monitor E-mail:
33.	Is a Contract Research Organization (CRO) involved in this research? If No, proceed to question 34.	Yes ☐	No ☐
33a.	CRO Name:		
34b.	When a CRO is involved, WIRB routinely sends approval documents to the CRO *instead of the sponsor,* not to both. Would the sponsor contact like copies sent to them *in addition to the copies sent to the CRO contact*?	Yes ☐	No ☐
33c.	CRO Address: (street, city, state/province, postal code, country)		
33d.	CRO Contact Name:	Gender: ☐ M ☐ F	
33e.	CRO Contact Phone: ( )	CRO Contact E-mail:	

III.	RESEARCH SITE LOCATIONS & INFORMATION (must match 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 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.
34.	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.) Name of Research Location: Physical Address: (street, city, state/province, postal code, country) (*must match part 3 of Canadian QIU form, if applicable*)
34a.	Site #1 Phone: ( )
34b.	What type of facility is this site? ☐ Medical office ☐ Hospital ☐ University ☐ Psychiatric Institution ☐ Nursing home ☐ Other (specify): _____ ☐ Research Clinic ☐ Dialysis Center
34c.	Does this site have an obligation to use another IRB? *Yes ☐ No ☐ *If Yes, • 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): _____
34d.	What resources are available at this site to treat emergencies resulting from study-related procedures? ☐ BLS trained personnel ☐ ACLS trained personnel and crash cart ☐ Emergency drugs and supplies to stabilize subject until emergency personnel arrive ☐ Emergency response team within facility ☐ Call 911 ☐ Other (specify): _____ ☐ N/A; explain: _____ and skip to question 34g.
34e.	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? _____
34f.	Does the PI or a sub-investigator have staff privileges at the facility to be used in an emergency? Yes ☐ *No ☐ *If No, you must attach a separate sheet of paper describing the following: • 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

34g.	For each additional site, please copy, complete and attach the Additional Site Listing form at the end of this document.	N/A ☐

35.	What is the local attitude toward human subject research? ☐ Positive ☐ Negative If other than positive, please explain:			
36.	Have there been any recent changes to laws governing medical research in your state/province? If yes, please provide whatever information you have.	Yes ☐	No ☐	unknown ☐
37.	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. What precautions will be used to ensure subject *privacy* is protected? (check all that apply) ☐ Use of drapes or other barriers for subjects who are required to disrobe. ☐ Research intervention is conducted in a private room. ☐ 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. ☐ Other (specify): _____			
38.	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.) What precautions will be used to maintain the confidentiality of identifiable information? (check all that apply) ☐ Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. ☐ Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. ☐ 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. ☐ Whenever feasible, identifiers will be removed from study-related information. ☐ Because the research involves web-based surveys, precautions are in place to ensure the data is secure by using passwords and encryption. ☐ Audio and/or video recordings of subjects will be transcribed and then destroyed to eliminate audible identification of subjects. ☐ Other (specify): _____			

39.	Please describe the roles of those members of the study team who have substantive interaction with subjects. Please note that all study staff (including principal investigators and sub-investigators) must have completed training in human subject research protection (see question 17a for more information). WIRB considers a Co-PI to be an Investigator that is equally sharing responsibility for the conduct of a research study under the regulations. Please note that WIRB staff will contact you to clarify the role of any study team member that is listed as a Co-PI.	
	Name/Site(s) / Title / Role *Example:* *John Doe, M.D., Sites #1 & #2* — *PI* — *Provide medical oversight for study subjects. Responsible for all study related issues*	
	Attach an additional page, if necessary.	
40.	Who will perform the screening examination of the patients to determine if they are eligible for the research? (if applicable)	N/A ☐

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.		
41.	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. ☐ Prisoners ☐ Minors (WIRB requires that subjects enrolled as minors be re-consented if they reach legal age of consent during their participation in the research. See the www.wirb.com FAQ on this topic for more information.) ☐ Poor/uninsured ☐ Institutionalized ☐ Limited or non-readers ☐ Wards of the state (e.g., foster children) ☐ Pregnant women (if yes, you must complete question 41a) ☐ Nursing home residents recruited in the nursing home ☐ Students of PI or study staff ☐ Students to be recruited in their educational setting, i.e., in class or at school ☐ Employees directly supervised by PI or sub-investigator ☐ Employees of research site or sponsor ☐ Military personnel to be recruited by military personnel ☐ Cognitively impaired (if yes, you must answer question 41b) ☐ Adult subjects who cannot consent for themselves; i.e., requiring consent by a legally authorized representative (if yes, you must answer questions 42a-c) ☐ Others vulnerable to coercion (specify):_____	*Yes ☐	No ☐
41a.	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 62): • 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 ☐
41b.	If some or all subjects will be cognitively impaired, describe how capacity for consent will be determined: ☐ Capacity assessment using the following method or instruments: _____ ☐ Other (specify): _____		N/A ☐
42.	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 42a, 42b, and 42c below. 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.	*Yes ☐	No ☐

42a.	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 ☐
42b.	Describe how you will verify that a given individual is qualified to serve as an LAR: ☐ Request documentation of authorization. ☐ Obtain verbal assurance from the LAR. ☐ Other (specify): _____		N/A ☐
42c.	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 ☐	N/A ☐
43.	Who will conduct the consent discussion with the subject? (Check all that apply) ☐ Principal Investigator ☐ Sub-investigator ☐ Research coordinator ☐ Other (specify): _____		
44.	Please describe the circumstances and location of the consent process: (check all that apply) ☐ N/A, waiver of consent requested (please complete one of the following WIRB forms: "Request for Full 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). ☐ In a private room ☐ In a waiting room ☐ In an open ward ☐ In a group setting ☐ In a group setting with follow up in a private room. ☐ In emergency situations. The process is as follows (explain here or attach a separate sheet): _____ ☐ Online, in public, over the phone, or in another unusual situation. The process is as follows (explain here or attach a separate sheet): _____ ☐ Other (specify): _____		

45.	How will you be sure there is sufficient opportunity for the subject to consider whether to consent? (check all that apply) ☐ 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.) ☐ Subjects will be allowed a waiting period of at least _____ hours to consider their decision. ☐ Other (specify): _____
46.	Describe steps taken to minimize the possibility of coercion or undue influence: (check all that apply) ☐ 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). ☐ Other (specify): _____
47.	Mark one of the following regarding waiver of rights during the consent process: ☐ 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. ☐ Other (specify): _____

48. 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.

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)

- ☐ This is minimal risk research for which compensation for injury language in the consent form is not necessary.
- ☐ There is no CTA for this research.
- ☐ This research is funded by a government agency (such as NIH) that does not offer compensation for injury.
- ☐ 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.
- ☐ 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.

_____ _____
Printed or Typed Name Company & title

_____ _____
Signature Date

(*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*.)

- ☐ The PI is affiliated with an institution which has required compensation for injury language (attach a copy of the language).
- ☐ 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: _____
- ☐ Other (explain): _____

49. Check any of the following methods that the PI will use to recruit subjects for this study:

- ☐ Advertising *(All recruitment materials must be approved by WIRB before use)*
- ☐ From a database for which subjects have given prior permission to be contacted for research studies
- ☐ From Personal Contact (e.g., patients, students)
- ☐ Referrals [*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.]*
- ☐ Other (specify): _____

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.

50. Please confirm that there are no plans to pay *referral fees* 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.)

- ☐ I confirm
- ☐ Other (explain) _____

51.	Are recruitment materials or subject materials attached? *If Yes, check all that are attached: ☐ Newspaper ☐ Letter ☐ Brochure ☐ Web Site ☐ Public Service Announcement ☐ **Video *(recordings will not be reviewed without scripts)* ☐ Posting ☐ **Audio *(recordings will not be reviewed without scripts)* ☐ Other _____ **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.	*Yes ☐	No ☐
51a.	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 ☐	No ☐
52.	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. 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.	*Yes ☐	No ☐
53.	Please describe the population from which you will recruit for this research: **If your site is in the U.S.:** (please round to nearest whole number) Race: (should add up to 100%) _____% Black or African-American _____% Asian _____% Native Hawaiian or other Pacific Islander _____% White _____% American Indian or Alaska Native _____% Other: _____ _____% Total (should equal 100%)		NA ☐ (inter-national sites only)
54.	**If your site is in the U.S.:** (please round to nearest whole number) Ethnicity: (should add up to 100%) _____% Hispanic or Latino _____% Not Hispanic or Latino _____% Total (should equal 100%) Note: WIRB uses race and ethnicity categories and guidance issued by NIH and FDA.		NA ☐ (inter-national sites only)
55.	**If your site is located outside the U.S.:** Please indicate the names and percentages of the applicable racial and/or ethnic populations.		NA ☐

56.	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 ☐	*No ☐
57.	Please indicate the language(s) of the subjects the PI plans to enroll. *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.* ☐ Languages: _____ Or ☐ The protocol prohibits enrollment of non-English speaking subjects.		
58.	If you are enrolling non-English speaking subjects, please explain the plans for translation: ☐ 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). All translations must be accompanied by a certification of translation. *Contact the WIRB Translations Department for requirements.* ☐ I would like WIRB to provide translation of the consent forms and/or other subject materials.* ***(translation fee applies)*** *If you would like WIRB to translate the documents, please list each item you would like translated and indicate the languages requested: Items: _____ Languages: _____		N/A ☐
58a.	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) ☐ 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. ☐ The research team has 24-hour access to a translation service with sufficient medical expertise to discuss the research in this study. ☐ Other (explain):_____ *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.*		N/A ☐

59.	Contact information to be listed in the Consent Form: Contact name and phone number for **questions about the study**: Name _____ Phone number(s): (____) _____ ☐ Office Hours ☐ 24 hours ☐ Pager (check all that apply) (____) _____ ☐ Office Hours ☐ 24 hours ☐ Pager (check all that apply) Contact name and phone number for use in the event of **research-related injury**: Name _____ Phone number(s): (____) _____ ☐ Office Hours ☐ 24 hours ☐ Pager (check all that apply) (____) _____ ☐ Office Hours ☐ 24 hours ☐ Pager (check all that apply) **The contact information provided above will be used to produce your final consent form(s)**; please ensure it does not conflict with the contact information listed in the consent form(s) you submit. 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. 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.	N/A ☐ (sites requesting waiver of consent only)
60.	WIRB routinely displays the name and contact information of the Principal Investigator and, if applicable, the Co-Principal Investigator in 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.** SUB-INVESTIGATOR(S): [first name last name, degree] [Phone number (optional)] STUDY COORDINATOR(S): [first name last name, degree] [Phone number (optional)] 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.	N/A ☐

61.	Please provide subject payment information: If subjects are to be paid, state specifically for which visits subjects will receive payment and when such payment will be made; for example, "payment will be made at the end of each study visit," "payment will be made at the end of the last study visit," or "payment will be made within one month after the last study visit". Please be as specific as possible to minimize confusion. ☐ Subjects will **not be paid**. OR ☐ Provide a statement for the consent form explaining the payment plan (amounts, visits not paid, when payment will be made). **If there are different consent forms for different populations or sub-studies, provide a payment statement for each.** *For example:* *You will be paid $____ for each completed study visit. If you do not complete the study, you will be paid for the visits you have completed. You will be paid at the end of each study visit [or "you will be paid within 30 days of the end of your participation in the study," etc.]* Note: **The payment information provided above will be used to produce your final consent form(s)**; please ensure it does not conflict with the information listed in the consent form(s) you submit.
V.	Investigator Confirmation of Board Requirements
62.	The Principal Investigator must assure the Board of the following by signing in the space provided below: • The answers in this form are accurate. • I will read and abide by all of the Board requirements listed on the Certificates of Approval (COAs) and other WIRB correspondence I receive. • If one or more of the Board's requirements are not acceptable, I understand that I may ask the Board to reconsider its requirements, but may not enroll subjects until the issue is resolved in a manner acceptable to the Board. _____ _____ Signature of Principal Investigator Date Please note that if you are filling out this form in Word, you'll need to print this page, obtain the PI's signature, and either fax it to us or scan the signed page and e-mail it to us.

VI.	BILLING INFORMATION: Please tell us who should be billed for this review. (If this section is not completed, the PI will be billed.)		
63.	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.		
63a.	Company Name:		
63b.	Attn.:		
63c.	Address: (street, city, state/province, postal code, country)		
63d.	Phone: ( )	E-mail:	
63e.	Mail Stop/Cost Center:		
63f.	Purchase Order number (P.O.#), if applicable:		N/A ☐
63g.	Cost of the requested WIRB translation services will be paid by: (if applicable)		N/A ☐
63h.	Please describe any special billing instructions:		N/A ☐

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.
64.	_____ _____ _____ Printed or Typed Name of Person Completing This Form* Date Company & title ( ) _____ _____ Phone number E-mail address (optional) **Please note that the person named above will not receive copies of approval documents unless they are also listed in this form as the study coordinator, SMO contact, etc.*

Initial Review Submission Form – *Additional Sites Listing* WIRB®

Sponsor Protocol #:_____ Investigator Last Name: _____

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

a.	Additional Site # 2: Name of Research Location: Physical Address: (street, city, state/province, postal code, country) (*must match part 3 of Canadian QIU form, if applicable*)		N/A ☐
b.	Site #2 Phone: ( )		
c.	What type of facility is this site? ☐ Medical office ☐ Hospital ☐ University ☐ Psychiatric Institution ☐ Nursing home ☐ Other (specify): _____ ☐ Research Clinic ☐ Dialysis Center		
d.	Does this site have an obligation to use another IRB? *If Yes, • 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 ☐	No ☐
e.	What resources are available at this site to treat emergencies resulting from study-related procedures? ☐ BLS trained personnel ☐ ACLS trained personnel and crash cart ☐ Emergency drugs and supplies to stabilize subject until emergency personnel arrive ☐ Emergency response team within facility ☐ Call 911 ☐ Other (specify): _____ ☐ N/A; explain: _____ 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: • 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 ☐	*No ☐
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 11)

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:

- ☐ Investigator
- ☐ Sub-Investigator
- ☐ Other Research Staff
- ☐ Immediate Family Member of PI or study staff (spouse or dependent children)
- ☐ Institution (e.g., Hospital, University, etc.)
- ☐ 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 12)

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 52)

WIRB®

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

Questions about the call center's practices:

3.	How is information stored at the call center? ☐ In a database. Describe the security measures in place: _____ _____ _____ ☐ On paper. How and where is the paper stored? _____ _____ _____ Who has access to the paper? _____ _____ _____		
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.	Does the call center sell or share the names of screened subjects to other entities? *If Yes, please explain:	*Yes ☐	No ☐
8.	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 ☐	No ☐

Questions about the site's practices:

9.	How is information stored at the site? ☐ In a database. Describe the security measures in place: _____ ☐ On paper. How and where is the paper stored? _____ Who has access to the paper? _____

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 ☐	*No ☐
13.	Does the site sell or share the names of screened subjects to other entities? *If Yes, please explain:		*Yes ☐	No ☐
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 ☐	No ☐	NA ☐

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.