

WIRB[®]

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



Initial Review Submission Form for Sponsors and CROs Instructions for Requesting Pre-Review of Materials for Multi-Center Studies

WIRB can assist sponsors and CROs during the planning stages of a multi-center study by pre-reviewing the protocol and subject materials, including the consent form. The fee for initial review applies.

If the Board finds the research as reviewed acceptable (“approvable”), the submitter is issued a letter documenting the Board’s determination, a redlined consent form indicating the Board’s changes to the consent, and appropriate documentation of the review of the other subject materials submitted.

Approvable research requires submission of an investigator for the research before *approval* can be granted. The research cannot go forward until an investigator is approved for the research.

The following is a general list of items needed by WIRB to conduct a pre-review:

- **WIRB Initial Review Submission Form for Approvables: “Initial Review Submission Form for Sponsors and CROs”** 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**
- **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** (may be omitted if WIRB is already in receipt of a current version)
- **Background Information for Food Supplements**
- **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.

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.

*WIRB routinely changes the approvable consent form in the following situations:

- When an individual investigative site submits unique consent form language for review with their initial submission materials and answers “No” to the submission form question that asks if the PI would like to use the previously approved consent form (“For **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 review, and may incorporate, the unique requested language. The site will therefore receive a unique version of the WIRB-approved consent form.

Sites that plan to use the approvable template language should not include a consent form document with their submitted review materials, and should answer “Yes” to the submission form question that states, “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?”

- When the research was found approvable by a U.S. panel, but a site based in Canada submits, the submission is reviewed by WIRB’s Canadian panel, which reviews and modifies consent forms according to Health Canada regulations. Language in consent forms approved by the Canadian panel may differ from the language in the approvable consent form as approved by a WIRB U.S. panel.

Sponsors of research involving multiple Canadian locations may benefit from requesting an “approvable” review by WIRB’s Canadian panel prior to submitting Canadian investigators for review.

- When an investigator at an institution submits, WIRB may modify the language in the approvable consent form to conform to the institution’s requirements.

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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.
- 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.

I. SPONSOR & PROTOCOL INFORMATION: Please tell us about the research to be conducted.				
1.	Protocol Number and Version Date:			
2.	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.)			
3.	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"/>	
4.	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"/>	
5.	Sponsor Name:			
5a.	Sponsor Contact Name:	Gender: <input type="checkbox"/> M <input type="checkbox"/> F		
5b.	Sponsor Contact Address: (street, city, state/province, zip, country)			
5c.	Sponsor Contact Phone: ()	Sponsor Contact Fax: ()	Sponsor Contact E-mail:	
5d.	Will this be the contact to receive approval documents for all investigators who submit under this protocol? Comments:	Unknown <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>

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5e.	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				
5f.	Medical Monitor Name: (first and last name, plus degree)	Gender: <input type="checkbox"/> M <input type="checkbox"/> F			
5g.	Medical Monitor Phone: ()	Medical Monitor Fax: ()	Medical Monitor E-mail:		
6.	Is a Contract Research Organization (CRO) involved in this research? If No, proceed to question 7.		Yes <input type="checkbox"/>	No <input type="checkbox"/>	
6a.	CRO Name:				
6b.	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"/>	
6c.	CRO Address: (street, city, state/province, zip, country)				
6d.	CRO Contact Name:	Gender: <input type="checkbox"/> M <input type="checkbox"/> F			
6e.	CRO Contact Phone: ()	CRO Contact Fax: ()	CRO Contact E-mail:		
6f.	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				
6g.	Will this be the contact to receive approval documents for all investigators who submit under this protocol? Comments:		Unknown <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>
6h.	Please provide any special CRO-related information or instructions:				
7.	Approximately how many sites do you anticipate sending to WIRB? _____ (Contact Client Services for information about special pricing for multi-site studies.)				
8.	Please indicate desired panel review(s): (check all that apply) <input type="checkbox"/> U.S. Panel <input type="checkbox"/> Canadian Panel* *Canadian sites are reviewed by WIRB's Canadian panel, which reviews and modifies consent forms according to Health Canada regulations. Language in consent forms approved by the Canadian panel may differ from the language in the consent form approved by a WIRB U.S. panel; therefore, sponsors of research involving multiple Canadian locations may benefit from requesting an "approvable" review by WIRB's Canadian panel prior to submitting Canadian investigators for review.				
9.	Has another IRB declined to review, tabled, deferred, disapproved or terminated this research prior to submission to WIRB? *If Yes, please provide the IRB correspondence.		*Yes <input type="checkbox"/>	No <input type="checkbox"/>	

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10.	Does the sponsor plan to submit the data to the United States Environmental Protection Agency (EPA)? *If Yes, WIRB will apply the additional regulatory requirements of the EPA regulations.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
11.	Is this research federally funded entirely or in part? If No, proceed to question 12. (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_irbervices_fed.aspx .)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
11a.	What federal agency(ies) is funding this research?	N/A <input type="checkbox"/>	
11b.	If this grant funds multiple protocols, please list those protocols previously reviewed by WIRB:	N/A <input type="checkbox"/>	
11c.	Provide a copy of the complete grant (if applicable).	N/A <input type="checkbox"/>	
11d.	Provide the federal contract (if applicable).	N/A <input type="checkbox"/>	
12.	Does this research involve a Drug, Biologic or Dietary Supplement? If No, proceed to question 13.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
12a.	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"/>	
12b.	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"/> 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.)		
12c.	Provide a copy of the Investigator's Drug Brochure (unless previously sent to WIRB), applicable package inserts, or the background information for food supplements. Comments:	N/A <input type="checkbox"/>	

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13.	Does this research involve an Investigational Device? *If Yes, proceed to question 13a.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
13a.	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 and the basis for that determination, 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"/>
14.	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 15.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
14a.	Has this been submitted to the Recombinant DNA Advisory Committee (RAC)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
14b.	If available, attach the Response to Appendix M of the National Institutes of Health (NIH) Guidelines.		N/A <input type="checkbox"/>
14c.	If available, attach copies of the RAC correspondence regarding the protocol.		N/A <input type="checkbox"/>
14d.	Has there been an Institutional Biosafety Committee (IBC) review? *If Yes, please attach the IBC recommendations.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
II. 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 (if known).			
15.	Would you like WIRB to write the consent form? (<i>extra fee</i>)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
16.	Are recruitment materials or subject materials attached? *If Yes, check all that are attached: <ul style="list-style-type: none"> <input type="checkbox"/> Newspaper <input type="checkbox"/> Brochure <input type="checkbox"/> Public Service Announcement <input type="checkbox"/> **Video (<i>recordings will not be reviewed without scripts</i>) <input type="checkbox"/> **Audio (<i>recordings will not be reviewed without scripts</i>) <input type="checkbox"/> Other _____ <input type="checkbox"/> Letter <input type="checkbox"/> Web Site <input type="checkbox"/> Posting **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 <input type="checkbox"/>	No <input type="checkbox"/>
16a.	Have any of these or similar recruitment materials been previously approved by WIRB for other protocols? *If Yes, please attach a copy of the previously-approved item(s). WIRB support staff will provide the Board with information about the previous Board review, so that the previous decision of the Board can be taken into account when the materials are reviewed.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>

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17.	<p>Please confirm that the sponsor/CRO has 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> <p><input type="checkbox"/> I confirm <input type="checkbox"/> Other (explain): _____</p>		
18.	<p>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.)</p> <p>*If Yes, report such incentives on the recruitment bonus disclosure form at the end of this submission form.</p>	<p>*Yes <input type="checkbox"/></p>	<p>No <input type="checkbox"/></p>
19.	<p>Please confirm that if the sponsor/CRO proposes <i>recruitment bonuses</i> during the course of this research study, that you will submit them for prior IRB review. (Recruitment bonuses are paid to persons involved in the research for screening / enrolling / maintaining participation of subjects.)</p> <p><input type="checkbox"/> I confirm <input type="checkbox"/> Other (explain): _____</p>		
20.	<p>Are you submitting any written or verbal screening materials for screening subjects prior to enrollment in the research (such as telephone call scripts, written or web-based questionnaires or pre-screening forms)?</p> <p>*If Yes, please include them for review (English documents only; see the translations question below for information about submitting documents in another language). Each site using the materials will need to submit the WIRB Screening Procedures Information form. WIRB reviews screening materials in the same fashion as consent documents.</p> <p>Please Note – for HIPAA compliance, U.S. PIs may need an authorization from the subject or a waiver of authorization before they can use or disclose identifiable health information for research screening or recruitment purposes. For more information on HIPAA requirements for research and additional HIPAA-related forms, go to www.wirb.com.</p>	<p>*Yes <input type="checkbox"/></p>	<p>No <input type="checkbox"/></p>
21.	<p>If non-English speaking subjects will be enrolled, please explain the plans for translation:</p> <p><input type="checkbox"/> After I receive the WIRB-approved consent form and subject materials, the approved documents will be translated and then the translations will be submitted with a certification of translation 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>	<p>NA <input type="checkbox"/></p>	

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21a.	<p>Please provide instructions for processing any requests for translations from participating sites:</p> <p><input type="checkbox"/> Process the translation as requested by the site.</p> <p><input type="checkbox"/> Do not process translations requested by sites without confirmation from the sponsor/CRO.</p> <p><input type="checkbox"/> Do not process any translations requested by sites.</p> <p><input type="checkbox"/> Other: (specify) _____</p>		<p>NA <input type="checkbox"/></p>
22.	<p>Please indicate here if you would like to preview documents that have been approved by the Board. If you mark "yes" here, WIRB will send each investigator's approval documents directly to the sponsor/CRO contact and hold the site's copies for three business days. This will give you a chance to review the documents before they are sent to the sites. (If you select "Yes," WIRB will apply the three-day hold throughout the life of the research.)</p>	<p>Yes <input type="checkbox"/></p>	<p>No <input type="checkbox"/></p>
23.	<p>Please provide subject payment information, if known: 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.</p> <p><input type="checkbox"/> Subjects will not be paid.</p> <p>OR</p> <p><input type="checkbox"/> 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.</p> <p><i>For example:</i></p> <p><i>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].</i></p> <p>Note: Your review may be delayed if we need to obtain clarification from you because the payment information in the consent form(s) you submit differs from the payment listed above.</p>	<p>NA <input type="checkbox"/></p>	

WIRB® Recruitment Bonus Disclosure Form (Follow-Up to Question 18)

Sponsor Name: _____ Sponsor Protocol No.: _____

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:
