



Western Institutional Review Board®
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 OHRP/FDA Parent Organization number: IORG0000432
 IRB registration number: IRB00000533



Change in Research and Subject Recruitment (Ads) Submission Form

Have you tried WIRB's new online "smart form" submission process?

Submitting via WIRB's electronic smart forms can significantly reduce the number of questions you have to answer.
 Go to www.wirb.com and click on WIRBNet to get started.

1.	Sponsor Name:	
2.	Sponsor Protocol Number:	WIRB Protocol Number:
3.	This change in research is submitted for <input type="checkbox"/> Principal Investigator name(s): _____ <i>*If you are submitting on behalf of multiple investigators, please make sure to include a complete listing of all investigators</i> or <input type="checkbox"/> Approvable review	

Please complete the sections of this form applicable to your Change in Research request:

- I. Changes to the protocol and/or consent form
- II. Additional or relocated site
- III. Recruitment materials (advertisements, web sites, public service announcements and screening scripts)
- IV. Subject Materials and Retention items (Subject Diaries, ID Cards, etc.)
- V. Planned Protocol Deviations
- VI. Requests for translations or approval of translated documents
- VII. Other review requests

I. Complete this section to submit changes to the protocol and/or consent form.

<u>Changes to the Protocol</u>		
4.	Does this Change in Research include a <i>protocol change (amendment, administrative change, etc.)</i> ? <i>*If yes, please indicate what items are included for review:</i> <input type="checkbox"/> Protocol amendment _____ (#, version, etc.), summary of changes, and the rationale for the change (if it is not included in the amendment itself) <input type="checkbox"/> Revised protocol version _____ (#, version, etc.), summary of changes, and the rationale for the change (if it is not included in the revision itself) <input type="checkbox"/> Administrative Letter dated _____ (#, version, etc.) and the rationale for the change (if it is not included in the letter itself)	<input type="checkbox"/> Yes* <input type="checkbox"/> No



Change in Research and Subject Recruitment (Ads) Submission Form (continued)

<u>Changes to the Consent Form</u>		
5.	<p>Are you requesting consent form changes?</p> <p><i>*If yes: If this is a multi-site study, WIRB might have already approved a revised consent form for a different site. The Board can approve the same changes for your site more quickly than it would take to approve language that is different. You can contact WIRB's Client Services at (800) 562-4789 or clientservices@wirb.com to find out if WIRB has reviewed these changes for a different site. If WIRB has already approved a revised consent form for this protocol, would you like WIRB to approve the previously approved changes for your site?</i></p> <p style="text-align: center;"><input type="checkbox"/> Yes (skip question 5a) <input type="checkbox"/> No</p> <p>Comments:</p>	<input type="checkbox"/> Yes* <input type="checkbox"/> No
5a.	<p>If you are requesting changes to a consent form, indicate which of the following you are submitting. You must provide a rationale for any changes not supported in the protocol (approval will be delayed if the Board isn't provided with a rationale for changes that are not related to the protocol):</p> <p><input type="checkbox"/> The requested changes clearly documented on a copy of the most recent WIRB-approved consent form. <i>and/or</i></p> <p><input type="checkbox"/> The requested changes clearly outlined in a document that indicates each change and the section of the consent form where the change should be made.</p> <p>Comments:</p> <p><i>Important Note: WIRB will not accept changes sent to us on the sponsor's template or other renditions of the consent form including previously-approved redlines. If the changes are submitted on a consent form, the consent form must be the most recent WIRB-approved version. You can obtain a copy of the consent form from WIRB's authenticated website at WIRB.com or by contacting Client Services at (800) 562-4789 or clientservices@wirb.com.</i></p>	
6.	<p>Would you like WIRB to provide translation for your new or updated consent form(s)?</p> <p><i>*If yes, you must also complete question 25.</i></p> <p>Please note if you have previously made arrangements for WIRB to translate study documents (Consent Forms, Subject Recruitment Material, Subject Diaries, etc), WIRB will continue to provide this service to your updated documents unless you indicate otherwise.</p> <p>Comments:</p>	<input type="checkbox"/> Yes* <input type="checkbox"/> No

II. Complete this section to submit an additional or relocated site.

Requests for additional or relocated sites where subjects will be seen are reviewed by Board. Changes to administrative sites do not need to be submitted for review. Consent Forms are updated accordingly upon approval.

If only your mailing address or other contact information has changed (not a site that subjects will be seen), you may use the Contact Information Update Form available on WIRB's website.

7.	<p>Are you requesting review of an additional or relocated site?</p> <p><i>*If Yes, please complete an Additional/Relocated Site Form for each new site (at the end of this form)</i></p>	<input type="checkbox"/> Yes* <input type="checkbox"/> No
7a.	<p>Are you also updating the delivery address for regulatory documents?</p> <p><i>*If Yes, please indicate on the Additional/Relocated Site Form(s) which address should be used for mailings.</i></p>	<input type="checkbox"/> Yes* <input type="checkbox"/> No



Change in Research and Subject Recruitment (Ads) Submission Form (continued)

8.	Will staff be added to the study team to cover the site(s)? *If no, skip the remainder of this section.	<input type="checkbox"/> Yes	<input type="checkbox"/> No*
9.	<p>Investigators must ensure that each member of the study team has had training in the protection of human subjects. Please indicate what type(s) of training the additional staff have completed (mark at least one, and all that apply):</p> <ul style="list-style-type: none"> <input type="checkbox"/> NIH online tutorial "Protecting Human Research Participants" <input type="checkbox"/> NCI Human Participant Protections Education for Research Teams <input type="checkbox"/> Institutional Human Subject Protection Training requirements satisfied <input type="checkbox"/> Tri Council Policy Statement online training (for Canadian sites) <input type="checkbox"/> Collaborative IRB Training Initiative (CITI) <input type="checkbox"/> WIRB-Sponsored Investigator or GCP course <input type="checkbox"/> N/A – this submission is for one of the following: <ul style="list-style-type: none"> <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): _____ <p>HIPAA training alone is not sufficient.</p> <p>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.</p>	N/A <input type="checkbox"/>	
10.	<p>Have any of the added <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?</p> <p>*If yes, has the conviction and/or discipline referenced above been reported to WIRB prior to this submission? <input type="checkbox"/> Yes <input type="checkbox"/> **No</p> <p>**If No, you must attach information about the incident and its outcome.</p>	<input type="checkbox"/> Yes*	<input type="checkbox"/> No or N/A
11.	<p>Financial conflict of interests: If any of the following are true for the new study staff or the new study staff's family, complete the <i>Financial Interest Disclosure Form</i> available at www.wirb.com and send it along with this submission.</p> <p><input type="checkbox"/> Yes, one or more of the following are true: (check all that apply and then complete the <i>Financial Interest Disclosure Form</i> available at www.wirb.com).</p> <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. <p><input type="checkbox"/> No, none of the above are true.</p>	<input type="checkbox"/> N/A	

III. Complete this section to submit recruitment materials such as advertisements, web sites, public service announcements and screening scripts

12.	Are you submitting revised versions of previously approved recruitment materials?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
12a.	<p>Are you submitting revised written or verbal screening materials? (such as telephone call scripts, written or web-based questionnaires or pre-screening forms)</p> <p>*If yes, you will need to either confirm below that the information you provided on the last Screening Procedures Information Form has not changed, or if the information has changed, indicate what aspect(s) of the plan has changed below (or via a new version of the form):</p>	<input type="checkbox"/> Yes*	<input type="checkbox"/> No
13.	<p>Are you submitting new recruitment materials?</p> <p>*If yes, answer question 13a. Comments:</p>	<input type="checkbox"/> Yes*	<input type="checkbox"/> No
13a.	<p>Have any of these materials been previously approved by WIRB for another investigator or another protocol?</p> <p>*If yes, indicate for which study and/or protocol they were approved: _____</p>	<input type="checkbox"/> Yes*	<input type="checkbox"/> No
14.	<p>Are you submitting any public service announcements?</p> <p>*If yes, indicate how the announcements will be used:</p> <p><input type="checkbox"/> announcer-read (verbatim) or <input type="checkbox"/> taped (for taped announcements, WIRB recommends requesting pre-review of the script and then submitting the final recording for approval).</p> <p>Comments:</p>	<input type="checkbox"/> Yes*	<input type="checkbox"/> No
15.	<p>Are you submitting any recruitment materials that reference a web site?</p> <p>*If yes, attach a hard copy of the recruitment sections of the web site for WIRB review (do not provide web site information that will not be used for recruitment).</p> <p>Comments:</p>	<input type="checkbox"/> Yes*	<input type="checkbox"/> No
16.	<p>Are you submitting new 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)?</p> <p>*If yes, you must describe the screening plan on the <i>Screening Procedures Information Form</i> found at www.wirb.com. WIRB reviews screening materials in the same fashion as consent documents. WIRB's requirements for screening scripts are listed at the bottom of the Screening Procedures Information Form.</p> <p>Comments:</p>	<input type="checkbox"/> Yes*	<input type="checkbox"/> No
17.	<p>Would you like WIRB to provide translation for your new or updated recruitment materials?</p> <p>*If yes, you must also complete question 25.</p> <p>Please note if you have previously made arrangements for WIRB to translate study documents (Consent Forms, Subject Recruitment Material, Subject Diaries, etc), WIRB will continue to provide this service to your updated documents unless you indicate otherwise.</p> <p>Comments:</p>	<input type="checkbox"/> Yes*	<input type="checkbox"/> No

IV. Complete this section to request review of subject materials and retention items such as subject diaries, ID cards, etc.

18.	Are you submitting revised versions of previously approved subject materials?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
19.	Are you submitting new subject materials? *If yes , answer question 19a. Comments:	<input type="checkbox"/> Yes*	<input type="checkbox"/> No
19a.	Have any of these materials been previously approved by WIRB for another investigator or another protocol? *If yes , indicate for which study and/or protocol they were approved: _____	<input type="checkbox"/> Yes*	<input type="checkbox"/> No
20.	Would you like WIRB to provide translation for your new or updated subject materials/retention items? *If yes , you must also complete question 25. Please note if you have previously made arrangements for WIRB to translate study documents (Consent Forms, Subject Recruitment Material, Subject Diaries, etc), WIRB will continue to provide this service to your updated documents unless you indicate otherwise. Comments:	<input type="checkbox"/> Yes*	<input type="checkbox"/> No

V. Complete this section to submit information to the Board about planned protocol deviations.

21.	Please describe the protocol deviation:
22.	Please describe how the action you plan to take is not consistent with the protocol:
23.	Please provide a rationale for taking this planned deviation:

VI. Complete this section to request approval of translated documents and/or to request WIRB provide a translation.

The consent forms and other applicable subject materials must be in a language easily understood by the subject and all translations must be approved by WIRB prior to use.

24.	Please indicate below the items included in this submission: <input type="checkbox"/> Translated Consent Form or other subject material is attached for review (<i>contact the WIRB Translations department for requirements</i>), or <input type="checkbox"/> I request WIRB provide a translation: Item(s): _____ Language(s): _____ Comments:
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Change in Research and Subject Recruitment (Ads) Submission Form (continued)

25. 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)

The plan for this research and language has already been submitted and accepted by WIRB.

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.*

26. Cost of the requested WIRB translation services will be paid by: (if applicable)

If you list someone other than yourself as the billing contact, please attach written verification from that person indicating he or she will pay for these services.

VII. Complete this section to request other types of review requests not covered in other sections (increases in subjects, etc.)

Please provide specific details about the request.

27. Other (explain):

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.

28.

_____ Printed or Typed Name of Person Completing This Form _____ Company/Title

_____ Phone number _____ Fax number _____ Date

_____ E-mail

**Please note that the person named above will not receive copies of approval documents unless specifically requested. If you would like to receive copies of approval documents, please complete the "Contact Information Update Form" available on the Download Forms page at www.wirb.com.*



Change in Research – Additional / Relocated Site Form

Sponsor Name: _____
Sponsor Protocol # _____

Investigator Last Name: _____
WIRB Protocol # _____

Submit a separate copy of this page for each additional or relocated site. List only sites at which subjects will be seen. Each site will be listed on the consent form.

a.	What type of site change does this concern? <input type="checkbox"/> Additional site or <input type="checkbox"/> Relocated site: This site replaces the site located at: _____. This change is effective as of date: _____. <input type="checkbox"/> This is a new mailing address		
b.	Site: 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>		
c.	Site Phone: ()		
d.	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		
e.	Does this site have an obligation to use another IRB? *If yes, WIRB will need a written statement from the other IRB acknowledging WIRB's review of this research. Please call Client Services for more information.	*Yes <input type="checkbox"/>	No <input type="checkbox"/>
f.	If this site is part of an organization which has a contract to use WIRB for IRB services, please provide the name of the organization:	N/A <input type="checkbox"/>	
g.	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		
h.	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? _____	N/A <input type="checkbox"/>	
i.	Does the PI or a sub-investigator have staff privileges at the facility to be used in an emergency? *If no, attach a separate sheet of paper describing the following: <ul style="list-style-type: none"> • How subjects would be referred for hospitalization, • Name, address and telephone number of physician who has agreed to attend these patients, and • What measures would be taken to assure communication between the investigator and the attending physician 	Yes <input type="checkbox"/>	*No <input type="checkbox"/>
j.	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:	N/A <input type="checkbox"/>	