



Change in Research and Subject Recruitment (Ads) Submission Form

1.	Sponsor Name: _____	
2.	Sponsor Protocol Number: _____	WIRB Protocol Number: _____
3.	This change in research is submitted by Principal Investigator <input type="checkbox"/> Yes* <input type="checkbox"/> No <i>*If yes, Principal Investigator name: _____</i> or Sponsor/CRO <input type="checkbox"/> Yes* <input type="checkbox"/> No <i>* If yes and you are submitting on behalf of multiple investigators, please attach a list of the investigators.</i>	

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> ? <input type="checkbox"/> Yes* <input type="checkbox"/> No <i>*If yes, please indicate what items are included for review:</i> <input type="checkbox"/> Protocol amendment _____, summary of changes, and the rationale for the change (if it is not included in the amendment itself) <input type="checkbox"/> Revised protocol version _____, summary of changes, and the rationale for the change (if it is not included in the revision itself) <input type="checkbox"/> Administrative Letter dated _____ and the rationale for the change (if it is not included in the letter itself)

	<u>Changes to the Consent Form</u>
5.	Are you requesting consent form changes? <input type="checkbox"/> Yes* <input type="checkbox"/> No <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> <input type="checkbox"/> Yes (skip question 5a) <input type="checkbox"/> No Comments: _____

5a.	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): <input type="checkbox"/> The requested changes clearly documented on a copy of the most recent WIRB-approved consent form. <i>and/or</i> <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. Comments: _____ <i>Important Note: WIRB will not accept changes sent to us on the sponsor's template or other renditions of the consent form. 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>
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6.	Are you requesting a consent form change due to a site's location changing or the addition of a site? <input type="checkbox"/> Yes* <input type="checkbox"/> No *If yes, complete the "Change in Research – Additional / Relocated Site Form" at the end of this document. Comments:
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II. Complete this section to submit recruitment materials such as advertisements, web sites, public service announcements and screening scripts

7.	Are you submitting revised versions of previously approved recruitment materials? <input type="checkbox"/> Yes <input type="checkbox"/> No
7a.	Are you submitting revised written or verbal screening materials? (such as telephone call scripts, written or web-based questionnaires or pre-screening forms) <input type="checkbox"/> Yes* <input type="checkbox"/> No *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):
8.	Are you submitting new recruitment materials? <input type="checkbox"/> Yes* <input type="checkbox"/> No *If yes, answer question 8a. Comments:
8a.	Have any of these materials been previously approved by WIRB for another investigator or another protocol. <input type="checkbox"/> Yes* <input type="checkbox"/> No *If yes, indicate for which study and/or protocol they were approved: _____
9.	Are you submitting any public service announcements? <input type="checkbox"/> Yes* <input type="checkbox"/> No *If yes, indicate how the announcements will be used: <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). Comments:
10.	Are you submitting any recruitment materials that reference a web site? <input type="checkbox"/> Yes* <input type="checkbox"/> No *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). Comments:
11.	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)? <input type="checkbox"/> Yes* <input type="checkbox"/> No *If yes, you must describe the screening plan on the Screening Procedures Information Form 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. Comments:

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III. Complete this section to submit information to the Board about planned protocol deviations. Planned protocol deviations that may adversely affect the rights, safety or welfare of subjects or the integrity of the research data should be submitted to WIRB for review and approval prior to implementation except where necessary to eliminate apparent immediate hazards to the human.

If your planned protocol deviation does NOT adversely affect the rights, safety or welfare of subjects or the integrity of the research data, you are not required to report the deviation to WIRB.

12. Please describe the protocol deviation:

13. Please describe how the action you plan to take is not consistent with the protocol:

14. Please provide a rationale for taking this planned deviation:

IV. 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.

15. Please indicate below the items included in this submission:

Translated Consent Form or other subject material is attached for review (*contact the WIRB Translations department for requirements*), or

I request WIRB provide a translation:

Item(s): _____

Language(s): _____

Comments:

16. 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.

V. 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.

17. Other (explain):

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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.

18.

Printed or Typed Name of Person Completing This Form

Company/Title

Phone number

Fax number

Date

E-mail

Change in Research – *Additional / Relocated Site Form*

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Sponsor Protocol # _____

Investigator Last Name: _____

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: _____.		
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.	Will staff be added to the study team to cover this site? *If no, skip to question h.	Yes <input type="checkbox"/>	*No <input type="checkbox"/>
e.	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): <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"/>	
f.	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? *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 **If No, you must attach information about the incident and its outcome.	*Yes <input type="checkbox"/>	No or N/A <input type="checkbox"/>

Change in Research – *Additional / Relocated Site Form*

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g.	<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.</p> <p><input type="checkbox"/> Yes, one or more of the following are true: (check all that apply and then complete the additional disclosure page at the end of this form)</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>	N/A <input type="checkbox"/>									
h.	<p>What type of facility is this site?</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 33%;"><input type="checkbox"/> Medical office</td> <td style="width: 33%;"><input type="checkbox"/> Hospital</td> <td style="width: 33%;"><input type="checkbox"/> University</td> </tr> <tr> <td><input type="checkbox"/> Psychiatric Institution</td> <td><input type="checkbox"/> Nursing home</td> <td><input type="checkbox"/> Other (<i>specify</i>): _____</td> </tr> <tr> <td><input type="checkbox"/> Research Clinic</td> <td><input type="checkbox"/> Dialysis Center</td> <td></td> </tr> </table>	<input type="checkbox"/> Medical office	<input type="checkbox"/> Hospital	<input type="checkbox"/> University	<input type="checkbox"/> Psychiatric Institution	<input type="checkbox"/> Nursing home	<input type="checkbox"/> Other (<i>specify</i>): _____	<input type="checkbox"/> Research Clinic	<input type="checkbox"/> Dialysis Center		
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<input type="checkbox"/> Psychiatric Institution	<input type="checkbox"/> Nursing home	<input type="checkbox"/> Other (<i>specify</i>): _____									
<input type="checkbox"/> Research Clinic	<input type="checkbox"/> Dialysis Center										
i.	<p>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.</p>	*Yes <input type="checkbox"/>	No <input type="checkbox"/>								
j.	<p>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:</p>		N/A <input type="checkbox"/>								
k.	<p>What resources are available at this site to treat emergencies resulting from study-related procedures?</p> <ul style="list-style-type: none"> <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 (<i>specify</i>): _____ <input type="checkbox"/> N/A 										
l.	<p>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? _____</p>		N/A <input type="checkbox"/>								
m.	<p>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:</p> <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"/>								
n.	<p>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:</p>		N/A <input type="checkbox"/>								