



706B West Ben White Blvd. Suite 210 Austin, TX 78704 TEL: 800-688-2132 FAX: 512-747-6012 www.rcrc-irb.com

GUIDANCE DOCUMENT: ADDITIONAL SITE OR SITE CHANGE

This guidance document is designed to assist in the completion of *FORM 140 Additional Site/Site Change*. The Principal Investigator must inform RCRC IRB of all changes to the information that was provided to RCRC IRB at the time of initial submission and approval. Submit the completed and signed *FORM 140* along with a cover letter requesting approval of the change or addition (e-mailed or fax cover sheet) to RCRC IRB. You may not implement any changes until you have received approval from RCRC IRB.

WHEN SHOULD THIS FORM BE SUBMITTED? This form must be completed and submitted to request approval of an additional research site and/or to notify RCRC IRB of a change in the location of a research site (i.e. when a physician physically relocates the practice office).

The submission deadline is 12:00 noon central time on THURSDAY. The completed *FORM 140 Additional Site/Site Change* and all supporting documents may be faxed to 512-747-6012; e-mailed to rcrc@rcrc-irb.com; or mailed to: RCRC IRB 706B West Ben White Blvd. Austin, TX 78704. Do not submit this guidance document.

INSTRUCTIONS FOR COMPLETING RCRC IRB FORM 140

	<ul style="list-style-type: none"> • Provide the name of the sponsor • Provide the protocol number
A. Submission Information	<ol style="list-style-type: none"> 1. Indicate whether this request is for adding a new site or changing a site address. 2. If this is for an investigational drug study, include the revised FDA Form 1572.
B. Updated or Current Investigator and Research Site Information	<ol style="list-style-type: none"> 1. Provide the complete name and credentials of the Principal Investigator. 2. Provide the name of the research site (i.e. business name of the practice or clinic) 3. Provide the name of the person who is the primary contact for all matters. 4. Provide the best phone number to reach the contact person. 5. Provide the complete mailing address for the primary contact person. 6. Provide the E-mail address of the primary contact person. 7. Provide the fax number for the primary contact person. 8. Provide a phone number where the Principal Investigator may be reached by study participants 24 hours a day.
C. Required Equipment, Emergency Medical Facility and Community Attitudes	<p>Depending on the nature of the study RCRC IRB may require that safety (rescue) equipment be available in each research facility where an investigational drug is being administered and/or investigational procedures are performed. If you believe this question does not apply to your research, (i.e. participants in an outpatient study taking study drug in pill form, device study, or other interventional study) indicate this in an attachment. RCRC IRB will make a final determination for required safety equipment.</p> <ol style="list-style-type: none"> 1. Describe the general attitude of the additional or new community. The PI must describe the general religious, economic, and ethnic viewpoints of the community from which your research participants will be drawn, and address how this could impact the conduct of the research at this site. Consider any recent or historical events covered by local media may influence a prospective participants' willingness to enroll in a research trial, or to trust researchers. In some communities the PI may need to address specific historical events influencing the current perspective of clinical research and researchers. The selection of participants should reflect the purposes of the research, and the group that will benefit from the research outcome. The proposed research should specify the gender and racial/ethnic composition of the participant population, if it differs from that of the general population of the area in which it will be conducted. Providing this information to a non-local IRB is essential to the protection of research

	<p>participants and is intended to contribute to the meaningful consideration of various local factors.</p> <ol style="list-style-type: none"> 2. Indicate whether injectable Benadryl® is available at <i>each</i> facility at which research procedures will take place. 3. Indicate whether injectable epinephrine is available at <i>each</i> facility at which research procedures will take place. 4. Indicate what additional equipment is available at <i>each</i> facility 5. Describe your plan, to treat medical emergencies and to provide care for a participant who suffers a research related injury. An agreement with the sponsor should stipulate who will provide this care and who will cover the cost of the care. 6. Provide the name and address of the hospital or medical facility that will be used to treat medical emergencies or provide psychological counseling for problems that occur at this site. If you utilize a 911 service, indicate that here. 7. Indicate the proximity of the closest emergency medical facility. The Board will specifically assess the ability of geographically remote sites to participate in a study relative to the level of risk and complexity of the protocol procedures. 8. Indicate whether the PI has privileges at this facility (for physician PI's). 9. For studies enrolling children indicate whether this facility is equipped to handle pediatric emergencies including counseling for psychological trauma.
<p>D. Additional Research Site Information and Transfer/Designation of IRB.</p>	<ul style="list-style-type: none"> • Provide information for the additional or new research site. • Indicate if any part of the research will be conducted in a <i>facility</i> that is under the jurisdiction of a local IRB. Facilities that usually have their own local IRB include (but are not limited to) universities, hospitals or similar facilities that often host research studies. If the answer to this question is "yes," then the Local IRB will need to defer authority to RCRC IRB in order for RCRC IRB to proceed with review of the research. This is accomplished by obtaining the signature of the IRB Chair or other signatory official of the facility.
<p>E. Principal Investigator Attestation Statement</p>	<p>The PI must attest to the accuracy of the information provided, and the sign the document.</p>