



706B West Ben White Blvd. Austin, TX 78704 TEL: 800-688-2132 512-747-9382 [www.rcrc-irb.com](http://www.rcrc-irb.com)

**GUIDANCE DOCUMENT: FINAL REPORT**

This guidance document is designed to assist in the completion of *FORM 130 Final Report*. The completion of a clinical investigation is a change in the study activity that must be reported to the IRB in accordance with [21 CFR 56.108(a)(3-4)]. RCRC IRB will review the Final Report to ensure that all safety information has been reported, and that all study participants have safely exited the protocol.

**WHEN SHOULD THIS FORM BE SUBMITTED?**

Use *FORM 130 Final Report* to notify RCRC IRB when all participants have completed protocol procedures and have exited the study as determined by the PI and/or the study sponsor. The completed report and all supporting documents may be faxed to 512-747-9382; e-mailed to [rcrc@rcrc-irb.com](mailto: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 130**

	<ul style="list-style-type: none"> <li>▪ Provide the name of the sponsor</li> <li>▪ Provide the protocol number.</li> </ul>
A. Protocol Information	<ol style="list-style-type: none"> <li>1. Provide the date on which the form was completed, all information is considered current as of this date.</li> <li>2. Provide the current expiration date of the study at this site.</li> </ol>
B. Investigator and Site Information	<ol style="list-style-type: none"> <li>1. Provide the complete name and credentials of the Principal Investigator.</li> <li>2. Provide the name of the research site (i.e. business name of the practice or clinic)</li> <li>3. Provide the complete mailing address for the primary contact person.</li> <li>4. Provide the name of the person who is the primary contact for all matters.</li> <li>5. Provide the E-mail address of the primary contact person.</li> <li>6. Provide the best phone number to reach the contact person.</li> <li>7. Provide the fax number for the primary contact person.</li> <li>8. Report any changes to the PI of the study that have not already been reported. Complete and submit <i>FORM 150 Principal Investigator Change</i> use <i>FORM 155</i> for guidance to request a separate review for approval of a new PI. These forms are available on our website <a href="http://www.rcrc-irb.com">www.rcrc-irb.com</a>. A change in PI must be approved before Continuing Review will be granted.</li> <li>9. Report any changes in the financial disclosure status or any changes in the business relationship between the PI and the Sponsor (including spouse, or dependent children). All salaried positions, retainers, profit sharing, or stock options must be disclosed. Routine study payments for professional services related to the study are not generally considered to create a conflict. The PI must verify that no changes have occurred. If changes have occurred they must be reported.</li> <li>10. Report any changes in the Board certification, licensure, or FDA debarment of the PI. The PI's current professional license must also be included with the submission. Note the expiration date of the license and ensure that a current license is submitted for our files PRIOR to expiration.</li> <li>11. Indicate any pending disciplinary action against the Investigator from the state licensing Board. RCRC IRB will verify this information.</li> </ol>
C. Study Status and Enrollment Information	<p>Indicate the status of the study that prompted this final report. If no participants were <i>consented</i> skip to section G. If the study is being closed for a reason <i>other</i> than those listed, describe the event that prompted the closure.</p> <ol style="list-style-type: none"> <li>1. Indicate the number of screen failures at this site.</li> <li>2. Indicate the number of participants who voluntarily withdrew their consent, and why.</li> <li>3. Indicate the number of participants who were withdrawn by the sponsor or principal investigator and why.</li> <li>4. Indicate the number of participants that completed protocol procedures.</li> <li>5. Indicate the number of participants that were consented (this should be the sum of rows 1-4).</li> </ol>

D. Participant Rights Information	<ol style="list-style-type: none"> <li>1. Report any concerns, questions, or complaints, raised by your study participants, and their resolution. This information helps the IRB evaluate the needs of study participants and to better protect their rights and safety.</li> <li>2. Consider the activity of the study at this site, and report any events that may have altered the original risk/benefit assessment such as unknown risks of specific study procedures; the number of required visits was too burdensome to participants resulting in a high drop-out rate; or the amount of compensation is inadequate due to increased transportation costs).</li> <li>3. Describe any circumstances where informed consent was not properly obtained and documented prior to enrollment.</li> <li>4. Indicate any observed benefit that participants have experienced while on study (with some research there is no expected benefit).</li> </ol>
E. Unanticipated Problems	<ol style="list-style-type: none"> <li>1. Indicate whether there have been any Unanticipated Problems involving risks to participants or others at this site since previous IRB review.</li> <li>2. Describe any new risks associated with the research drug, device, or procedures that have been identified at this site or study wide.</li> <li>3. Indicate whether any participants have withdrawn their consent due to Unanticipated Problems involving risks to participants or others.</li> <li>4. If Unanticipated Problems involving risks to participants or others have been identified, the PI must indicate in his/her own words, which has been <i>most frequent</i>, based on his/her observation of the study activity.</li> <li>5. If Unanticipated Problems involving risks to participants or others have been identified, the PI must indicate in his/her own words which has been the <i>most severe</i>, based on his/her observation of the study activity.</li> <li>6. If Unanticipated Problems involving risks to participants or others have been identified, the PI must indicate in his/her own words the association of these events to those initially anticipated (i.e. frequency, severity, character) at the outset of the research.</li> </ol> <p><b>Note: All Unanticipated Problems involving risks to participants or others must be reported to RCRC IRB using FORM 300. You may include any previously unreported unanticipated problems involving risks to participants or others simultaneously with this Continuing Review Report. However, they must be reported on FORM 300 (see FORM 310 for additional guidance), within the required reporting timeframe. Do not submit reports of events that RCRC IRB does not accept for review.</b></p>
F. Audit and Monitoring Information	<ol style="list-style-type: none"> <li>1. Indicate whether the <i>site</i> has been inspected or monitored by an independent monitoring board, and attach the site specific monitoring report if available.</li> <li>2. Indicate whether the <i>site</i> has had an FDA inspection and attach the report if available.</li> <li>3. For multi-site studies: Indicate whether there have been any multi-center trial reports, summaries, and/or interim findings and attach if available. Please contact the Sponsor to obtain this report. Reviewing information related to the conduct of the research at all sites in a multi-site study, ensures appropriate management of information obtained in multi-site research, that may be relevant to the protection of participants at all sites.</li> <li>4. Indicate whether there have been any recent publications in literature or professional journals and attach if available.</li> </ol>
G. PI Certification Statement	The Principal Investigator must sign the application and attest to the accuracy and validity of the information provided on the report.
H. List of Attachments	Use this final checklist to ensure that all required attachments are included with your submission. <b>Failure to submit all required attachments will result in a delay of your review, and may result in suspension or termination of the research</b>
I. IRB Assessment	THIS SECTION FOR RCRC IRB USE ONLY