

## Study Closure Submission

- In SpartaIRB, continuing reviews, closures, and modifications are submitted using the same form.
- When completing this form: **choose carefully**. You cannot change your responses to the question regarding the type of form you are completing. If you select the wrong purpose, you may end up having to discard your submission.
- It is recommended that all information be readily available prior to completing the SmartForm in the SpartaIRB electronic system. This includes but is not limited to: number of subjects enrolled total, in the last year, and at all study sites, milestones of the research, non-compliance events, available reports/results, etc.

## How do I submit a Study Closure?

<p><b>Step 1</b></p>	<p>Log into SpartaIRB: <a href="https://spartaIRB.case.edu">https://spartaIRB.case.edu</a>. Navigate to the study that you wish to submit a closure for.</p>
<p><b>Step 2</b></p>	<p>On the left-hand side of the screen, select “Create Modification/CR”</p>

<p><b>Step 3</b></p>	<p>On the first page of the SmartForm, select <b>Continuing Review</b> if you intend to close the study.</p> <p><b>Hint:</b> Please be prepared to accurately select the type of form you wish to submit. Once you hit “continue,” you will be unable to revise your selection, so please choose carefully.</p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p style="text-align: center;"><b>Modification / Continuing Review / Study Closure</b></p> <p><b>* What is the purpose of this submission? ?</b></p> <p><input checked="" type="radio"/> Continuing Review</p> <p><input type="radio"/> Modification</p> <p><input type="radio"/> Modification and Continuing Review</p> <p><a href="#">Clear</a></p> </div>																
<p><b>Step 4</b></p>	<p>On the second page of the SmartForm, fill in the information. Please note: <b>You need to check the first four research milestones to close the study.</b> An acknowledgement that the study will be closed will be presented after the first four milestones are checked.</p> <p><b>Continuing Review / Study Closure Information</b></p> <p><b>1. * Specify enrollment totals:</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;"></th> <th style="width: 20%;">Subjects Enrolled</th> <th style="width: 10%;">Total</th> <th style="width: 10%;">Since Last Approval</th> </tr> </thead> <tbody> <tr> <td>Estimated number of subjects to be enrolled in the coming year:</td> <td></td> <td><input type="text" value="0"/></td> <td></td> </tr> <tr> <td>At this investigator's sites: ?</td> <td><input type="text" value="10"/></td> <td></td> <td><input type="text" value="5"/></td> </tr> <tr> <td>Study-wide: ?</td> <td><input type="text" value="10"/></td> <td></td> <td></td> </tr> </tbody> </table> <p><b>2. Research milestones:</b> (select all that apply)</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Study is permanently closed to enrollment OR was never open for enrollment</li> <li><input checked="" type="checkbox"/> All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)</li> <li><input checked="" type="checkbox"/> Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)</li> <li><input checked="" type="checkbox"/> Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)</li> <li><input type="checkbox"/> Remaining study activities are limited to data analysis</li> <li><input type="checkbox"/> Study remains active only for long-term follow-up of subjects</li> <li><input checked="" type="checkbox"/> Study open for enrollment</li> </ul> <p><b>! Important!</b> If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight. For multicenter sites, check with the sponsor/lead site before requesting closure.</p> <p><b>* I acknowledge that this study will be closed:</b> <input checked="" type="checkbox"/></p> <p><b>3. * Do any investigators or research staff have a financial interest related to the research that was not described in a previous application? ?</b></p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p>		Subjects Enrolled	Total	Since Last Approval	Estimated number of subjects to be enrolled in the coming year:		<input type="text" value="0"/>		At this investigator's sites: ?	<input type="text" value="10"/>		<input type="text" value="5"/>	Study-wide: ?	<input type="text" value="10"/>		
	Subjects Enrolled	Total	Since Last Approval														
Estimated number of subjects to be enrolled in the coming year:		<input type="text" value="0"/>															
At this investigator's sites: ?	<input type="text" value="10"/>		<input type="text" value="5"/>														
Study-wide: ?	<input type="text" value="10"/>																

	<p><b>4. Check the items that are true since the last IRB approval for all sites involved in the study:</b> (initial review or last continuing review)</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> NO subjects experienced unexpected harm</li> <li><input type="checkbox"/> Anticipated adverse events have NOT taken place with greater frequency or severity than expected</li> <li><input checked="" type="checkbox"/> NO subjects withdrew from the study</li> <li><input checked="" type="checkbox"/> NO unanticipated problems involving risks to subjects or others</li> <li><input checked="" type="checkbox"/> NO complaints about the study</li> <li><input checked="" type="checkbox"/> NO publications in the literature relevant to risks or potential benefits</li> <li><input checked="" type="checkbox"/> NO interim findings</li> <li><input checked="" type="checkbox"/> NO multi-center trial reports</li> <li><input checked="" type="checkbox"/> NO data safety monitoring reports</li> <li><input checked="" type="checkbox"/> NO regulatory actions that could affect safety and risk assessments</li> <li><input checked="" type="checkbox"/> NO other relevant information regarding this study, especially information about risks</li> <li><input checked="" type="checkbox"/> In the opinion of the PI, the risks and potential benefits are unchanged</li> <li><input checked="" type="checkbox"/> All modifications to the protocol have been submitted to the IRB</li> <li><input checked="" type="checkbox"/> All problems that require prompt reporting to the IRB have been submitted</li> </ul> <p><b>5. Attach supporting documents:</b> (include an explanation of each item left unchecked above) ?</p> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <p><input type="button" value="+ Add"/></p> <p style="text-align: center;">Name</p> <hr/> <p><input type="button" value="Upload Revision"/> Adverse event log.xlsx <input type="button" value="x"/></p> </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <p> <input type="button" value="« Back"/> <input type="button" value="Save"/> <input type="button" value="Exit"/> <input type="button" value="Hide/Show Errors"/> <input type="button" value="Print"/> <input type="button" value="Jump To"/> <input style="border: 2px solid red;" type="button" value="Continue »"/> </p> </div> <p>Click Continue.</p>
<p><b>Step 5</b></p>	<p>Click Finish</p>
<p><b>Step 6</b></p>	<p>Click "Submit" on the left-hand side of your screen, and click OK after reading the attestation. Please note: only the PI and PI proxy(ies) can submit.</p> <p><b>Hint:</b> Use the process flow diagram to determine where your submission is in the review process. Your assigned IRB coordinator will be listed under the "IRB Coordinator" item at the top of the page.</p>

More questions? Contact the Institutional Review Board:

UH IRB at 216-844-1529

CWRU IRB at 216-368-6925