Use this form to close research at a site. *(For HUD use closures, use the* [*HUD Closure Form*](https://www.wcgclinical.com/wp-content/uploads/2020/08/HRP-253.doc)*)*

If your answer does not fit in the space provided, you may refer to and submit separate attachments.

***Blank & incomplete answers to required questions will result in delayed reviews.***

# Identifying Information:

|  |
| --- |
| Investigator Name:  |
| Sponsor's protocol ID *(if applicable):*  | IRB protocol number/tracking number*:* |
| Sponsor:  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Are **all** the following true at your site?* The research is permanently closed to enrollment at your site.
* All subjects have finished all procedures required by the protocol. (e.g., interventions, tests, monitoring, visits, phone calls, post-card contacts, and collection of data from medical or other records)
* The sponsor or sponsor representative has indicated that you can immediately close your site, and
* If the research was conducted under a Federalwide Assurance, analysis of private identifiable information and identifiable biospecimens at the site is completed.
 | Yes[ ]  | **\*No****[ ]**  |
|  | **\*If no**, are all the following true at your site?* Oversight of the research has been transferred to another IRB.
* The other IRB has approved the research.
 | Yes[ ]  | **\*No****[ ]**  |
|  | **\*If no**, stop. You cannot close if answering NO to BOTH 1 and 2 above. Please submit at a time when you can answer one of the above questions Yes. |

# The following questions apply to your site only. "You" refers to you or your research team. Since study startup:

|  |  |  |
| --- | --- | --- |
|  | How many subjects have you **enrolled in the research**?*("Enrolled" means consent was obtained. If consent is not required, "enrolled" means included in the research.)* | **0** |
| For the enrolled subjects reported in the line above:  |  |
|  | How many subjects **failed screening**? *(Enter 0 if the protocol does NOT involve screening.)* | **0** |
|  | How many subjects **decided on their own to stop** taking part in the research? Summarize the reasons why subjects decided to stop taking part in the research: | **0** |
|  | How many subjects did you **remove from the research** before reaching a study endpoint?*(Do not count subjects who failed screening.)*Summarize the reasons why you withdrew/discontinued subjects from the research: | **0** |
|  | How many subjects are **lost to follow-up**? *(Are no longer reachable.)* | **0** |
|  | How many subjects **completed the research**? *(“Completed" means the subject is no longer participating in the research and has either completed all research procedures or reached a study endpoint.)* | **0** |
|  | Total subjects remaining on the Study: **\*Subjects remaining on study at closure must be zero** (unless you have transferred oversight to a different IRB - see [question 2 above](#oversight)).This total is auto-calculated as follows: Remaining subjects **=** Number enrolled **–** (screen failed**+**stopped**+**removed**+**lost to follow up**+**completed): **If the number shown here is not zero, please review the numbers inserted above to accurately reflect the breakdown of subjects enrolled, withdrawn, completed, Etc.**  | **\*0** |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Have you received any complaints from subjects or others about the study that have NOT yet been reported to this IRB?**\*If yes**, Describe the complaints and include in this submission any relevant documentation or correspondence:  | **\*Yes**[ ]  | No**[ ]**  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Is there any information that required reporting per IRB [**'POLICY Prompt Reporting Requirements'**](https://www.wcgclinical.com/wp-content/uploads/2020/08/IRB.POL_.HRP_.071-Prompt-Reporting-Requirements_v4.0_website.pdf) that has NOT yet been reported to this IRB?**\*If yes**, complete and submit a [Promptly Reportable Information form](https://www.wcgclinical.com/wp-content/uploads/2024/06/PRI_HRP-204.docx) with this submission.  | **\*Yes**[ ]  | No**[ ]**  |
|  | Have you implemented any change to the protocol, consent, or materials seen by subjects that this IRB has NOT yet approved?**\*If yes**, complete and submit a [Promptly Reportable Information form](https://www.wcgclinical.com/wp-content/uploads/2024/06/PRI_HRP-204.docx) with this submission. | **\*Yes**[ ]  | No**[ ]**  |

# Special Instructions:

|  |
| --- |
| Provide any special instructions or additional relevant information for this submission: |

# Acknowledgements:

By submitting this form, I confirm and understand the following acknowledgements.

* The information within the submitted documents is accurate and complete.
* I am authorized to submit on behalf of the sponsor or the PI.
* The PI has full awareness of the information within this form.
* ***PAYMENT* *TERMS: Invoices are due net 30 days unless otherwise agreed to in writing. Late payments may be subject to a monthly finance charge of 1.5% of the amount owed from the due date until payment in full. WCG IRB shall be entitled to recover all reasonable attorneys' fees, costs and expenses associated with any efforts to recover payment for overdue invoices.***

# 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.

|  |
| --- |
|  Name of Person Completing This Form Date  Company & Title Phone number E-mail address  |