**Instructions:**

Use this form to report Continuing Review data for each participating site. The form must be completed and sent to the overall study/lead UMN PI or their designee. Note that, if you do not provide this completed report to the overall study/lead UMN PI in a timely fashion when the information has been requested from the participating site, this may delay approval to continue study activities.

1. UMN IRB Study Number: Click or tap here to enter text.
2. Local Site ID Number: Click or tap here to enter text.
3. **Specify enrollment totals:**

|  |  |  |
| --- | --- | --- |
| **Participants Enrolled** | **Total** | **Since Last Approval (initial review or last continuing review)** |
| At this p-Site: |  |  |

1. **Check the items that are true for this p-Site since the last IRB approval (initial review or last continuing review):**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  | NO participants experienced unexpected harm | | --- | --- | |  | Anticipated adverse events have NOT taken place with greater frequency or severity than expected | |  | NO participants withdrew from the study | |  | NO unanticipated problems involving risks to participants or others (UPIRTSOs) | |  | NO complaints about the study | |  | NO publications in the literature relevant to risks or potential benefits that would influence participants' willingness to continue | |  | NO interim findings | |  | NO multi-center trial reports | |  | NO data safety monitoring reports | |  | NO regulatory actions that could affect safety and risk assessments | |  | NO other relevant information regarding this study, especially information about risks | |  | The PI has determined that the risks and potential benefits are unchanged | |  | PI made NO modifications to the protocol without IRB approval | |  | The PI has NO outstanding IRB reporting requirements that should have been submitted previously, including the prompt reporting of protocol deviations, allegations of non-compliance and audits, inspections, or inquiries by a federal agency. | |  |  | |

1. **Include an explanation for each item left UNCHECKED above. Also, include any other pertinent information of which the overall study/lead UMN PI should be aware.**

Click or tap here to enter text.

1. **P-Site PI Attestation**

By signing below as the p-Site PI, I attest that this progress report for this p-Site to be submitted to UMN IRB for the purposes of continuing review of the overall study is accurate.

p-Site PI Signature: Click or tap here to enter text.