Instructions: Use this form to request a Modification for a p-Site. You must send this completed form, along with any revised site documents (e.g., revised informed consent document) to the overall study/lead UMN PI or their designee. Note that you may not incorporate the requested modification into your study activities until you have received approval from the UMN IRB unless when immediate action must be taken to eliminate an apparent, unexpected hazard to the research participant.

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. **Site enrollment status:**

|  |
| --- |
|[ ]  No participants have been enrolled |
|[ ]  Participants have been enrolled |
|[ ]  All participants have completed all study-related interventions |
|[ ]  Site is permanently closed to enrollment |
|[ ]  Collection of private identifiable information is complete |

1. **Notification of participants:** (check all that apply)

|  |
| --- |
|[ ]  Current participants will be notified of these changes |
|[ ]  Former participants will be notified of these changes |

1. **Summarize the modifications:**

|  |
| --- |
| Click or tap here to enter text. |