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| **Use to request a modification to previously approved site activities[[1]](#footnote-1)***(Make copies of pages as needed)* |
| **Study IRB Number:** (if known) |       |
| **Study Title:** |       |
| **Short Title:** |       |
|  **Site Investigator:** |       |
| **Site Primary Contact:** |       |
| **Site Enrollment Status***Check all that are true* |
|[ ]  No subjects have been enrolled to date. |
|[ ]  Subjects are currently enrolled. |
|[ ]  The study is permanently closed to enrollment at my site. |
|[ ]  All subjects enrolled at my site have completed all study related interventions and interactions, including interventions and interactions related to collection of long-term follow-up data. |
|[ ]  No additional identifiable private information about the subjects is being obtained by me. |
| **Notification of subjects** |
|[ ]  Current subjects will be notified of these changes. | *If either is checked, ensure that the submitted documents describe how current or former subjects will be notified.* |
|[ ]  Former subjects will be notified of these changes. |  |
| **Site Information** |
| Provide the following documents when they exist or are applicable and have been modified:* Point-by-point response *(For a response to modifications to secure approval, deferral, or disapproval)*
* Evaluation of any Related Financial Interest.
* Written materials to be provided to or meant to be seen or heard by subjects at your site
	+ Evaluation instruments and surveys1
	+ Advertisements *(printed, audio, and video)*
	+ Recruitment materials and scripts
	+ Consent documents
	+ If consent will not be documented in writing, a script of information to be provided orally to subjects
	+ Foreign language versions of the above
* Site supplement to the main protocol
 |
| **Investigator Acknowledgement** |
| I will conduct this protocol in accordance with requirements this IRB’s requirements and any relevant local requirements. |
| Investigator signature | Date |
|       |  |

1. This document satisfies AAHRPP element I-9 [↑](#footnote-ref-1)