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| --- | --- | --- | --- | --- |
| **Use to request a modification to previously approved site activities**  *(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 |
|  | | | |  |