Complete this form if the device has been modified (e.g., battery replacement; lead revision etc). If the entire device is explanted, complete the Devices Log.

1: Device Revision/Replacement Log Details Table

| Line # | Device (link to line# on Devices Log) | Date of Revision (m m/d d/y y y y) | INS | Lead (LEFT) | Lead (RIGHT) if applicable | Extension (LEFT) if applicable | Extension (RIGHT) if applicable | Other | Clinical Condition If applicable, reason for the device revision/replacement |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Explant and replace on same day  Explant only  Replacement only (previously explanted)  Repositioned  Model # of new INS:  \*\*Device registration # of new INS: | Explant and replace on same day  Explant only  Replacement only (previously explanted)  Repositioned  Model # of new lead:  \*Device registration # of new lead: | Explant and replace on same day  Explant only  Replacement only (previously explanted)  Repositioned  Model # of new lead:  \*Device registration # of new lead: | Explant and replace on same day  Explant only  Replacement only (previously explanted)  Repositioned  Model # of new extension:  \*Device registration # of new extension: | Explant and replace on same day  Explant only  Replacement only (previously explanted)  Repositioned  Model # of new extension:  \*Device registration # of new extension: | Explant and replace on same day  Explant only  Replacement only (previously explanted)  Repositioned  Model # of new component:  \*\*Device registration # of new component: | Serious Adverse Device Effect, specify:  Intolerable Stimulation Related Adverse Event, specify:  Other Adverse Event, specify:  Inadequate Seizure Control  Other, specify: |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Explant and replace on same day  Explant only  Replacement only (previously explanted)  Repositioned  Model # of new INS:  \*\*Device registration # of new INS: | Explant and replace on same day  Explant only  Replacement only (previously explanted)  Repositioned  Model # of new lead:  \*Device registration # of new lead: | Explant and replace on same day  Explant only  Replacement only (previously explanted)  Repositioned  Model # of new lead:  \*Device registration # of new lead: | Explant and replace on same day  Explant only  Replacement only (previously explanted)  Repositioned  Model # of new extension:  \*Device registration # of new extension: | Explant and replace on same day  Explant only  Replacement only (previously explanted)  Repositioned  Model # of new extension:  \*Device registration # of new extension: | Explant and replace on same day  Explant only  Replacement only (previously explanted)  Repositioned  Model # of new component:  \*\*Device registration # of new component: | Serious Adverse Device Effect, specify:  Intolerable Stimulation Related Adverse Event, specify:  Other Adverse Event, specify:  Inadequate Seizure Control  Other, specify: |

## GENERAL INSTRUCTIONS

This CRF Module is intended to collect details about how a participant's/ subject's implanted device is modified (e.g., battery replacement, lead revision, etc.) while enrolled in a study. If the entire device is explanted, the Devices Log CRF Module should also be used.

The model and device number should be recorded. Reasons for replacement and/or revision must be specified for the device. Any Adverse Event (AE) that occurred prior to revision or replacement must also be recorded in the AE Tracking Log. Add additional rows and indicate page number for additional devices.

The form may be modified so that a separate CRF is filled out at each study visit, rather than maintaining a running log.