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)[ ] RepositionedModel # of new INS:\*\*Device registration # of new INS: | [ ] Explant and replace on same day[ ] Explant only[ ] Replacement only (previously explanted)[ ] RepositionedModel # of new lead:\*Device registration # of new lead: | [ ] Explant and replace on same day[ ] Explant only[ ] Replacement only (previously explanted)[ ] RepositionedModel # of new lead:\*Device registration # of new lead: | [ ] Explant and replace on same day[ ] Explant only[ ] Replacement only (previously explanted)[ ] RepositionedModel # of new extension:\*Device registration # of new extension: | [ ] Explant and replace on same day[ ] Explant only[ ] Replacement only (previously explanted)[ ] RepositionedModel # of new extension:\*Device registration # of new extension: | [ ] Explant and replace on same day[ ] Explant only[ ] Replacement only (previously explanted)[ ] RepositionedModel # 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)[ ] RepositionedModel # of new INS:\*\*Device registration # of new INS: | [ ] Explant and replace on same day[ ] Explant only[ ] Replacement only (previously explanted)[ ] RepositionedModel # of new lead:\*Device registration # of new lead: | [ ] Explant and replace on same day[ ] Explant only[ ] Replacement only (previously explanted)[ ] RepositionedModel # of new lead:\*Device registration # of new lead: | [ ] Explant and replace on same day[ ] Explant only[ ] Replacement only (previously explanted)[ ] RepositionedModel # of new extension:\*Device registration # of new extension: | [ ] Explant and replace on same day[ ] Explant only[ ] Replacement only (previously explanted)[ ] RepositionedModel # of new extension:\*Device registration # of new extension: | [ ] Explant and replace on same day[ ] Explant only[ ] Replacement only (previously explanted)[ ] RepositionedModel # 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.