Complete this form if the participant/subject has an implantable device that is currently providing therapy.

Table for Recording Implanted Devices Log Details

| Line # (link to line# on Devices Log form) | Device Type | Start Date(mm/dd/yyyy)Stop Date(mm/dd/yyyy) | Amperage (mA)Voltage (V) | Frequency (Hz) | Pulse Width (uSec) | Stimulation Duration ON (mins) | Stimulation Duration OFF (mins) | Positive Electrode Count(#) If applicable | Negative Electrode Count(#) If applicable | If applicable, reason for modifying parameters or electrode configuration | Comments |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| # | Data to be entered by site. | //// | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | [ ]  Serious Adverse Device Effect(s), specify:[ ]  Intolerable Stimulation Related Adverse Event, specify:[ ]  Other Adverse Event, specify:[ ]  Inadequate Seizure Control[ ]  Other, specify: | Data to be entered by site. |
| # | Data to be entered by site. | //// | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | [ ]  Serious Adverse Device Effect(s), specify:[ ]  Intolerable Stimulation Related Adverse Event, specify:[ ]  Other Adverse Event, specify:[ ]  Inadequate Seizure Control[ ]  Other, specify: | Data to be entered by site. |

## General Instructions

This Case Report Form (CRF) Module is used to collect data from participants/subjects who have implantable devices that are currently providing therapy. The CDEs on this CRF are highly recommended for all Prospective Intervention studies. Additional data about the implantable devices should also be recorded on the Devices Log CRF Module.

The device field line should correspond with the Devices Log Form, using the same line number for both forms. The devices that are implanted and providing therapy are the only devices that need to be recorded on the Implanted Devices Log. If applicable, the electrodes’ location should be specified under the electrodes’ fields.

Adverse Events (AE) caused by implanted devices will have modified parameters which must be specified on the form. Additional information can be recorded in the Comments field.

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