Complete this form if the participant/subject has utilized an implantable device based therapy for their epilepsy either in the past or ONGOING.

Table for Recording Device Data Details

| Line # | Device Name | Date of Initial Implant  (m m/dd/yyyy) | Device Manufacturer | Device Registration # or Serial # | Stimulation Target | Type of Lead (Depth; Strip; VNS) and # of Contacts (if applicable) | Location of Neurostimulator | [[1]](#footnote-1)Date of Permanent Explant (if applicable)  (m m/dd/yyyy) | Is any part of the device left in the body? | If applicable, Reason for Discontinuation |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| # | VNS  DBS  RNS  Other, specify: | // | Data to be entered. | INS  Lead  Extension (if applicable): | Left Vagus Nerve  Hippocampus  Left side  Right side  AN  Unilateral  Bilateral  Other, specify: | VNS  Depth; # Contacts  Strip; # Contacts  Other, specify: | Right Chest  Left Chest  Other, specify: | // | No  Yes  If Yes, specify: | Serious Device Adverse Effect(s), specify:  Intolerable Stimulation Related Adverse Event, specify:  Other Adverse Event, specify:  Inadequate Seizure Control  Other, specify: |
| # | VNS  DBS  RNS  Other, specify: | // | Data to be entered. | INS  Lead  Extension (if applicable): | Left Vagus Nerve  Hippocampus  Left side  Right side  AN  Unilateral  Bilateral  Other, specify: | VNS  Depth; # Contacts  Strip; # Contacts  Other, specify: | Right Chest  Left Chest  Other, specify: | // | No  Yes  If Yes, specify: | Serious Device Adverse Effect(s), specify:  Intolerable Stimulation Related Adverse Event, specify:  Other Adverse Event, specify:  Inadequate Seizure Control  Other, specify: |

## General Instructions

This Case Report Form (CRF) Module is used to collect data from participants/subjects who have utilized an implantable device based therapy for their epilepsy in the past, or are currently using an implantable device. The CDEs on this CRF are highly recommended for all Prospective Intervention studies. Additional data about implantable devices providing ongoing therapy should also be collected on the Implanted Devices Log CRF Module.

The device name and manufacturer must be specified in the Log. If any part of the device was left inside the body after explant, it must be recorded in the log along with the location of the part. Discontinuation of a device must also be addressed along with reasoning for discontinuation and any adverse events should be reported on the Adverse Event CRF.

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

1. If not explanted, complete Implanted Devices Log [↑](#footnote-ref-1)