Adverse Event Report

Patient Identifier: [Use anonymized code] **Date of Report:** [YYYY-MM-DD] **Reporter Name/Role:** [e.g., Dr. Juan Sales – Neurosurgeon] **Institution:** [e.g., General University Hospital Alicante]

1. Adverse Event Description

- **Event Title:** [Brief summary, e.g., Seizure after DBS lead implantation]
- **Date/Time of Onset:** [YYYY-MM-DD, HH:MM]
- **Detailed Description:**

[Describe the AE in detail, including symptoms, clinical findings, and progression.]

- **Outcome:**
  - [ ] Recovered
  - [ ] Recovering
  - [ ] Not Recovered
  - [ ] Permanent Damage
  - [ ] Death
  - [ ] Unknown
- **Date of Resolution (if applicable):** [YYYY-MM-DD]

2. Product / Intervention Involved

- **Product/Device Name:** [e.g., Medtronic Percept PC]
- **Type:** [e.g., Implantable Neurostimulator]
- **Lot / Serial Number:** [if available]
- **Dosage / Settings:** [if medication or programmable device]
- **Date of Use/Implantation:** [YYYY-MM-DD]

3. Patient Background

- **Age:** [Years]
- **Sex:** [Male / Female / Other]
- **Relevant Medical History:**

[Summarize significant comorbidities or past diagnoses.]

- **Concomitant Medications:**

[List all current medications, dosages, and frequencies.]

4. Causality Assessment

- **Relationship to Product/Intervention:**
  - [ ] Not Related
  - [ ] Unlikely
  - [ ] Possible
  - [ ] Probable
  - [ ] Definite
- **Rationale:**

[Explain reasoning for causality judgment.]

5. Action Taken

- [ ] Discontinued product/intervention
- [ ] Dose adjustment
- [ ] Supportive treatment
- [ ] Surgical intervention
- [ ] None
- **Describe in detail:**

[Explain actions taken in response to the AE.]

6. Regulatory Reporting

- **Reported to National Authority:** [ ] Yes [ ] No
- **Date of Submission:** [YYYY-MM-DD]
- **Reference Number (if any):** [Insert if received]
- **Additional Notes or Follow-up Plans:**

[Include monitoring strategies, further tests, or committee reviews planned.]

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