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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. Date of Report:** *(dd/mm/yyyy)* | \_\_\_\_/\_\_\_\_/\_\_\_\_\_ | | | **2. Report Type:** | | | Initial  Follow-up  Final | | |
| **3. Principal Investigator:** | | **Name:** Joanne A. de Hullu **Institute:** Radboudumc Nijmegen | | | | | | | |
| 4. Date of Onset (Serious) Adverse Event: | | | | | | \_\_\_\_/\_\_\_\_/\_\_\_\_\_(dd/mm/yyyy) | | | |
| **6. Event/Reaction:**  **Grade (1-5):** | | | | | | | | | |
| **7. Describe event:** *(Summary of signs and symptoms, diagnosis, treatment of event (type and duration), concurrent treatment, other relevant medical history, duration of prolongation of hospitalization, duration of ICU admission, number and duration re-admissions, additional control visits (specialist/nurse). Please include the point in the study at which the event occurred.)*  **Treatment arm:** Standard (RRSO) Experimental (RRS with DO) | | | | | | | | | |
| **8. Is the adverse event a Serious AE?**  YesNo  **9. If yes, category of the SAE:**  death  disability/incapacity  life-threatening  required hospitalization  required prolongation of hospitalization  required intervention to prevent permanent impairment  other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | **10. Relationship of (serious) adverse event to the experimental treatment (RRS with delayed RRO):**  1 = unrelated  2 = unlikely  3 = possible   4 = probable   5 = definite | | | | |
| **10. What is the outcome of the (S)AE?**  Recovered  Recovered with sequalae  Continuing  Resulted in Death  Unknown | | | | | **11. Date event resolved** *(dd/mm/yyyy)****:*** | | | | \_\_\_\_/\_\_\_\_/\_\_\_\_\_  Not applicable |
| **12. Date patient died** *(dd/mm/yyyy)****:*** | | | | \_\_\_\_/\_\_\_\_/\_\_\_\_\_  Not applicable |
| **13. Signature and function Person completing report:** | | | **Print Name:** | | | | | **Date (dd/mm/yyyy):** | |
| **14. Signature Principal Investigator:** | | | **Print Name:** | | | | | **Date (dd/mm/yyyy):** | |
| **PLEASE EMAIL COMPLETED FORM TO THE TUBA-WISP II STUDY GROUP AT THE RADBOUDUMC WITHIN 24 HOURS AFTER ONSET OF SAE:** [**TUBA-WISP@RADBOUDUMC.NL**](mailto:TUBA-WISP@RADBOUDUMC.NL) | | | | | | | | | |