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| --- | --- | --- | --- |
| **1. Date of Report:** *(dd/mm/yyyy)* | \_\_\_\_/\_\_\_\_/\_\_\_\_\_ | **2. Report Type:** | **[x]**  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?** **[ ]** Yes **[ ]** No**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** |