**Study Completion/Final Report Form**

(Filled by the Principal Investigator)

| **CNU-ERC Code:** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Project Title:** | | | | | | |
| **Principal Investigator:** | | | | | | |
| **Sponsor:** | | | | | | |
| **Summary of protocol participants:** | | | | | |  |
| Total accrual of trial | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Total patient to be recruited (CNU-ERC ceiling) | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Screened | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Screen failures | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Enrolled | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Consent withdrawn | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_ Reason: (Attach in format below) | |
| Withdrawn by PI | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_ Reason (Attach in format below) | |
| Active on treatment | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Completed treatment | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Patients on follow-up | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Patients lost to follow-up | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Any other | | | | |  | |
| Any impaired participants | | | | | □ NONE \_\_\_\_\_\_\_\_\_\_\_\_\_  □ Physically \_\_\_\_\_\_\_\_\_\_\_\_\_  □ Cognitively \_\_\_\_\_\_\_\_\_\_\_\_\_  □ Both \_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **Reason for Withdrawal:** | | | | | | |
| **Total no. of study arms:** | |  | | | | |
| **Study materials:** | |  | | | | |
| **Treatments form:** | |  | | | | |
| **Study dose(s):** | |  | | | | |
| **Duration of the study:** | |  | | | | |
| **Objectives:** | | | | | | |
| **Results in brief (use another sheet if more space is required):** | | | | | | |
| **Presentation/publication related to the data generated in this study:** | | | | | | |
| **SAE (total number and type):** | | | | | | |
| **Whether SAEs intimated to the CNU-ERC:** | | | | □ NO  □ YES | | |
| **Protocol deviations/violations (number and nature)** | | | | | | |
| **Conclusion:** | | | | | | |
| **Signature of PI:**  **Date (dd/mm/yyyy)** |  | | | | | |

| **ASSESSMENT OF PROJECT REPORT** | | | |
| --- | --- | --- | --- |
|  | | | |
| **Decision** | | | |
| □ Noted | | □ Requires more information | |
|  | | | |
| **PRIMARY REVIEWER** | Signature | | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| Date: <dd/mm/yyyy> | Name: | | <Title, Name, Surname> |
|  |  | | |