HREC ANNUAL REPORT

 ***(to be submitted* *by 30 April each year)***

**Study Reference Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Contact Person: ­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Sponsor (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Note:**

This Annual Report forms the basis of the extension of ethics approval by the Human Research Ethics Committees of Metro North Hospital and Health Service and is used by HRECs to fulfil some of their monitoring responsibilities in accordance with section 5.1.27 of the National Statement on Ethical Conduct in Human Research (the National Statement). Please complete all questions as accurately as possible.

|  |  |  |
| --- | --- | --- |
|  | **Information Required** | **Responses / Comments** |
| 1 | What year did this study commence | *Insert year* |
| 2 | Is this study a clinical trial? | *Yes / No* |
| 3 | Proposed number of participants to be recruited  | *Number to be Recruited:* |
| 4 | Actual number of participants recruited to date | *Number to Date:* |
| 5 | Number of participants recruited at each site | Site……………………….. *Number:*Site……………………….. *Number:*Site……………………….. *Number:* |
| 6 | Please indicate the versions and dates of the Protocol and Participant Information Sheet & Consent Form (PICF) currently being used in the study |   Version Date*Protocol:* *PICF:*  |
| 7 | Have there been any serious adverse events (SAEs), significant safety issues (SSIs), or suspected unexpected serious adverse reactions (SUSARs) associated with the study to date? | *Yes / No* |
| 8 | If you answered ‘Yes’ to Question 7 have all SAEs, SSIs or SUSARs been notified to the sponsor within 24 hours of becoming aware of the event? If you answered ‘No’, please move on to Question 9. | *Yes / No* |
| 9 | Have you encountered any problems conducting this study? | *Yes / No* |
| 10 | If you answered ‘Yes’ to Question 9, please provide details  | *(Max 200 words)* |
| 11 | Have there been any complaints regarding the conduct of the study? | *Yes / No* |
| 12 | If you answered ‘yes’ to Question 11, please provide details  | *(Max 200 words)* |
| 13 | Progress to Date *(Please attach a summary of findings to date; list of publications/presentations, etc.)* |  |
| 14 | Is this the final progress report for this study?*(If ‘Yes’ – please advise the HREC once the study has completed/closed and provide an Outcomes Report to the relevant Research Governance Office)*  | Yes / No |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_ / \_\_\_\_ / \_\_\_\_**

**Signature of Principal Investigator Date**