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| **CABRINI RESEARCH GOVERNANCE (CRGO) PROGRESS REPORT** |  |
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| **1** **Project reference no:** **2** **Project title:**  | **3 Commencement date:** **4 Expected completion date:**  **5 Third party studies**\* **at Cabrini:** YES [ ]  or NO [ ] **5** **Current status:**  [ ]  Recruiting  [ ]  Recruitment ceased  [ ]  Analysis complete  [ ]  Project closed [ ]  Project can be archived Specify Archive Duration\*: (\*per study protocol and Cabrini Data Management Policy)  |
| **6** **Please provide a brief statement of progress so far and results (if any). Please also indicate number of participants targeted, screened, screen-failed, enrolled, withdrawn, reasons for withdrawal etc. Is the study proceeding as anticipated? If not, why not? What challenges have emerged?**  *If more space is required, please attach a separate sheet.* *For a MULTI-SITE study, provide total study numbers below:*# targeted: # screened: # screen-failed: # currently enrolled: # withdrawn:*Provide study numbers specific to CABRINI / third party*\* *below:*# targeted: # screened: # screen-failed: # currently enrolled: # withdrawn:       |
|  **7 Have there been any changes to project methodology, data management or personnel?** Yes[ ] No[ ] If **Yes,** have they been approved by: a) the lead HREC? Yes[ ] No[ ] b)CRGO Yes[ ] No[ ] Provide a summary of main changes in the past 12 months:    If changes have not been approved, please note that you are in breach of your ethics and governance approval. Please provide a protocol amendment or letter informing the lead HREC and CRGO of the changes. |
| **8 Have any ethical issues/reportable adverse events emerged in the course of the project for:** (a) Participant(s) Yes [ ]  No[ ]  (b) Researcher(s) Yes[ ]  No[ ]  (c) Site(s) Yes[ ]  No[ ] If **Yes** (to any), have the Cabrini guidelines regarding notification been followed? Yes [ ] No [ ]  If these events have not been notified, please provide details to the CRGO on a separate sheet. |
| **9 Have there been any complaints about the project?** Yes [ ] No[ ]  If **Yes,** please detail of the nature of complaint(s) on a separate sheet. |
| **Industry-Sponsored Study/Clinical Trial****10 Have you reviewed safety information available to date**  **(including periodic safety reports) provided by study sponsor?** Yes [ ] No[ ] Study continues as planned [ ] Study amended to address safety concerns [ ] (separate submission made for amendment) |
| **11 Have you provided an updated insurance certificate?** Yes [ ] No [ ] Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **12 How has Cabrini Health been acknowledged in the promotion of this research?**1. **As a**

Funder [ ]  Participating Site [ ]  Author Affiliation [ ]  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. **In a**

Manuscript [ ]  Publication [ ]  Poster Presentation [ ]  Oral Presentation [ ]  Other\_\_\_\_\_\_\_\_\_\_\_\_\_*Provide copies and details of acknowledgements below:*     |
| **13 Has there been any secondary use, re-use or data sharing of the data set (in parts or whole) collected for this project?** Yes [ ] No[ ] *Provide details of the secondary use and / or data sharing activities below:*     |
| **14 If analysis is complete, have you attached a detailed report of findings / any publication(s) arising from the project?** Yes [ ] No[ ] *If no, provide rationale below:*   |
| **15 Can you recommend a participant from this study who would be amendable to participating in one or some of the following:**a) Providing a consumer story on their research experience which can be used for research promotion?Yes [ ] No[ ] b) Completing a research consumer feedback survey?Yes [ ] No[ ] c) Joining a research committee as a consumer representative?Yes [ ] No[ ]  |
| **Statement**I confirm that this project is being conducted as originally approved by the lead HREC (where applicable) and Cabrini Research Governance Office (and subject to any subsequently approved changes). Principal Investigator name: ……………………………………………………………………Principal Investigator signature: ……………………………………………………………… Date: / / |

*\* Third party studies are coordinated by non-Cabrini trials units (e.g. VMO rooms, external research groups) which may or may not access Cabrini services and may target non-Cabrini participants. Cabrini is not listed on the CTN as a participating site nor is a party to the CTRA.*