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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 Please also indicate number of participants targeted, screened, screen-failed, enrolled, withdrawn, reasons for withdrawal etc.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MULTI-SITE study, provide total study numbers below:*  # targeted: # screened: # screen-failed: # currently enrolled: # withdrawn:  *Provide study numbers specific to CABRINI / third party*\* *below:*  # targeted: # screened: # screen-failed: # currently enrolled: # withdrawn: | | |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?** YesNo  If **Yes,** have they been approved by: a) the lead HREC? YesNob)CRGO YesNo  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.*