# **Cabrini Research Data Governance Checklist**

This questionnaire is to be completed for each database or registry held and governed by Cabrini Health and any Clinical Quality Registry seeking access to Cabrini Health patient information.

**Project details:**

|  |  |  |  |
| --- | --- | --- | --- |
| Project title: |  | | |
| Principal Investigator: |  | Data manager or collector: |  |
| Department: |  | | |
| Funding source: |  | Funding amount: |  |
| Start date:  (DD/MM/YYYY) |  | End date:  (DD/MM/YYYY) |  |
| Purpose of data collection (short paragraph): |  | | |

**Ethical review of the project:**

|  |  |  |  |
| --- | --- | --- | --- |
| Is ethics approval required for your project?  Please use the [Risk Assessment Checklist](https://www.cabrini.com.au/research/research-with-us/ethics-and-governance/) as a reference if unsure. | Research Governance Office review only  HREC review  Not applicable | HREC or RGO reference number (if applicable): |  |
| Does data identify First Nations people or community? | | Yes  No | |

**Data Management**

Please provide a data dictionary including fields descriptions, options, data source for each field, link between fields, permissible values and ranges.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Dimension | Questions |  |  |  |  | |
| Eligibilities Criteria | Inclusion criteria: |  | | | | |
| Exclusion criteria: |  | | | | |
| Comments: | | | | | |
| Data Collection | Data collection methodology: (location of data collection, mechanism of data capture, tools for data capture, timing of data collection, identity, and qualifications of data collectors) |  | | | | |
| Type of data collection: | Clinical Quality Registry (*disease specific, multi-site data collection that reports on patient care and outcomes)*  Quality Assurance project  Research Database  Operational Database (*database to support research operations)*  Other, please specify: | | | | |
| What is the level of identifiability of the data collected in the database or registry? | Identifiable data *(data that enables the identification of a specific individual)*  De-identified data *(information that is no longer about an identifiable individual or an individual who is reasonably identifiable)*  Non-identifiable data *(data that has never had identifiers collected with or attached to it, or has had all identifiers permanently removed)* | | | | |
| Comments: | | | | | |
| Data Verification | What is the process to identify data errors/mistakes/omissions? |  | | | | |
| How will errors be corrected? |  | | | | |
| Data verification method: | software checks (ex REDCap data Quality)  off-line validation for permissible values  third party data validation  manual review of data  Other, please specify: | | | | |
| Comments: | | | | | |
| Data Repository Management | Data storage location(s): | REDCap hosted at Cabrini or  externally  Custom designed platform, please specify:  eCaptis  Excel spreadsheet  Other, please specify: | | | | |
| Security measures in place: | Password protection  Behind Cabrini Firewall  Encryption at rest  Encryption in transit (e.g: SFTP or Kiteworks, if other please specify)  Two Factor Authentication used  Other, please specify: | | | | |
| Who has access to the data: |  | | | | |
| How is access determined by security levels and user class? |  | | | | |
| How is access logged and monitored? |  | | | | |
| Data is indexed to optimise search and reporting |  |  |  | |  |
| Data Backups description (location, frequency of backups, protection of back up, etc): |  | | | | |
| Data retention period: | Less than 12 months  1 to 2 years  5 years  Up to 15 years  15 years or more  Permanently | | | | |
| Data archiving process (description of location, protection, etc) |  | | | | |
| Processes for the destruction of data in digital or paper format: |  | | | | |
| Comments: | | | | | |
| Data Analysis | Description of the data analyses plans (including fields and algorithms used, purpose and audience, qualifications of analysts, mechanism to statistically validate analysis, peer review prior to release, etc): |  | | | | |
| Data Reporting | How is the data used | Morbidity and Mortality Meetings  Multi-Disciplinary Meetings  Research Project  Reporting and Auditing  Other, please specify | | | | |
| Are there any reports generated from the database? | Yes  No  Later | | | | |
| What is the nature of the report and who is the audience(s) of the report? |  | | | | |
| What is the process and frequency for distribution of reports? |  | | | | |
| What is the level of confidentiality of reports? |  | | | | |
| How is the identity of patients and clinicians is protected? |  | | | | |
| Comments: | | | | | |
| Data Sharing | Are there any plans on sharing data or granting access to data for secondary use? | Yes  No  If yes, please specify: | | | | |
| Description of security, confidentiality, encryption of shared data: |  | | | | |
| Comments: | | | | | |
| Data Linkages | Where data is linked with other data collections, what is the process? |  | | | | |
| What elements will be linked? |  | | | | |
| Description of the security of any data linkages: |  | | | | |
| Comments: |  | | | | |

**For Clinical Quality Registries:**

|  |  |
| --- | --- |
| ACSQHC Reference Number: |  |
| What quality reports are sent back to Cabrini Health? | individual clinician  aggregated hospital data  other, please specify: |
| Who is this report sent to? (Please select all that apply) | Site Principal Investigator Research Governance Office  Site coordinator  Clinical governance |
| How often are these reports sent? |  |
| What arrangements are currently in place between the craft group, Quality Assurance and Cabrini Health to review these reports? |  |
| How is this funded? |  |
| How is the data collected and entered in the CQR? |  |
| Are there deficiencies in data entry? |  |
| What quality assurance processes support this? | Multi-Disciplinary Meetings  Morbidity and mortality meetings  Craft group review  None  Other, please specify |
| What can Cabrini Health do to further support these processes? |  |
| Are there agreed guidelines for review of clinical outliers in this process? |  |

Any concerns or clarifications should be raised with:

Dr Stefanie Elbracht-Leong, Data Governance and Registries Manager:

[email-datagovernance@cabrini.com.au](mailto:email-datagovernance@cabrini.com.au)

[sleong2@cabrini.com.au](mailto:sleong2@cabrini.com.au)