# **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

sleong2@cabrini.com.au