The Colorectal Cancer (CRC) Database project at the Cabrini Monash University Department of Surgery has been implemented to capture clinical research data on adult colorectal cancer surgical patients. The database provides:

- Real time clinical information for the provision of optimal patient care.
- Identification of patients at particular surgical risk to ensure that the risk is minimised.
- Information for future patients to assist them in making fully informed consent to medical procedures as part of their treatment regime.

The Colorectal Cancer Database Governance Committee has been established to maintain governance and overall management of the colorectal cancer database. The responsibilities of the Committee include:

1. Overseeing database management, including:
   1.1. Data ownership, access and privacy.
   1.2. Collection.
   1.3. Auditing and data integrity checking.
   1.4. Data analysis.
   1.5. Linkage with other established registries and research.
   1.6. Database development and infrastructure.
   1.7. Security and backups.

2. Reviewing and approving requests from Hospitals/Consultants to join the database based on a set of minimum requirements (see below).
   2.1. Each new user must complete an agreement and checklist – refer to appendix 1.

3. Reviewing and approving data access and analysis requests.
   3.1. Data access will be in the form of a research proposal with accompanying ethics approval.
   3.2. Data will be de-identified to support privacy and confidentiality.

4. Reviewing and approving data collaboration initiatives with other data repositories/institutions.

5. Reviewing and approving database development change requests.

6. Overseeing funding and resources including project management, hospital site data managers and database development/infrastructure support.

Committee Members
● Head of Cabrini Monash University Department of Surgery  
  o Associate Professor Paul J McMurrick  
● Director of Monash University CCRE Therapeutics  
  o Associate Professor Chris Reid  
● Participating Hospital /Consultant Representatives  
  o Cabrini Health: Peter Carne  
  o Alfred Hospital and Avenue Hospital: Stephen Bell  
  o Peninsula Health (Frankston Hospital): Stewart Skinner  
● cc Executive Director of Cabrini Institute, Cabrini Health.  
  o Professor Peter Lowthian

Requirements to Join the Database

The Committee will only approve requests to join the database where a Hospital/Consultant can demonstrate that they can meet the minimum requirements. The Database Manager is required to liaise with the Hospital/Consultant Representative to ensure that the joining requirements are understood and met.

Minimum Joining Requirements

1. **Ethics approval** to collect data – approval is required from the joining hospital and Cabrini Human Research Ethics Committee. This approval should specify and agree to identified patient data being housed within the database at Monash University Department of Epidemiology and Preventative Medicine.

2. **A sustainable process** for the ongoing collection and entry of data - this includes the following:
   2.1.1. Consultant/Resident hospital staff commitment to provide, enter and check data.  
   2.1.2. A Data Manager to support the Consultants/Residents data entry and ongoing data management and to liaise with the Database Manager on a regular basis.  
   2.1.3. Data Manager access and training on the hospital patient records system.  
   2.1.4. Computer and workspace infrastructure for the Data Manager.

3. **Ability to match a minimum dataset** (MDS) for the database.  
   3.1. Note that the minimum dataset is yet to be finalised and a MDS specific interface is yet to be developed.

4. **Ability to provide total Hospital/Consultant colorectal cancer patient numbers** as a baseline comparison of the database patient numbers.

5. **Agreement on database training and support** for the Consultants/Residents and Data Manager.
APPENDIX 1 – Checklist and sign-off to join the database

The following checklist is to be completed by the Database Manager and signed off by the Data Governance Committee and Joining Hospital/Consultant Representative.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Criteria Met</th>
<th>Comments</th>
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<tbody>
<tr>
<td>1. Ethics approval.</td>
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<td>2. Sustainable process and resources.</td>
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<tr>
<td>2.1. Consultant/Resident hospital staff commitment to provide, enter and check data.</td>
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<td>2.2. Data Manager.</td>
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<td>2.3. Data Manager access and training on the hospital patient records system.</td>
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<td>2.4. Data Manager computer and workspace infrastructure.</td>
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<td>4. Provision of total colorectal cancer numbers.</td>
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<td>5. Agreement for training and support.</td>
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Approval

To be completed prior to the database access being granted to the joining Hospital/Consultant.

<table>
<thead>
<tr>
<th>Sign-off</th>
<th>Name</th>
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<tbody>
<tr>
<td>Database Manager</td>
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<tr>
<td>Data Governance Committee</td>
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<tr>
<td>Hospital/Consultant Representative</td>
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<td>Date joined:</td>
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