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**CLINICAL REGISTRY APPLICATION FORM**

**Purpose:** This application form is to be used to provide details of a clinical registry seeking to obtain health information pertaining to Eastern Health patients or clients. This form is to be completed by external parties and/or Eastern Health clinical staff regardless of the size and scope of the Registry. The information provided on this form will assist Eastern Health to decide whether to approve participation in an external Registry or to create a local registry.

**Definition:** A Clinical Registry is a structured collection of data, including clinical outcomes and process measures, for a defined clinical condition. They include large externally hosted and maintained registries down to small locally-hosted registries maintained by Eastern Health personnel. A Clinical Quality Registry (CQR) is larger in scale and likely to be state-wide, national or international in scope. For the purposes of this form, Clinical Quality Registry and Clinical Registry are synonymous.

Any subsequent research studies arising from a Registry data collection must seek the appropriate Eastern Health Research and Ethics approval.

1. **REGISTRY OVERVIEW**

|  |  |
| --- | --- |
| **Registry Name** (formal name) |  |
| **Abbreviation** (if applicable) |  |
| **Clinical Stream or Focus** |  |
| **Registry Website** (if applicable) |  |
| **Registry Scope** | External Registry [ ]  Local Eastern Health Registry [ ]  |
| **Institution where the Registry is managed** |  |

Brief summary of the aims of the Registry in plain language *(no more than 50 – 100 words)*

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1. **CONTACT INFORMATION**
	1. **Registry Clinical Lead**

**\* For external registries, both the external contact and the Eastern Health contact are required**

|  |  |
| --- | --- |
| Title and Name |  |
| Appointment/Position |  |
| Department & Institution |  |
| Phone |  |
| Email |  |
| Relationship to Eastern Health | None [ ]  Current employee [ ]  Dual Appointment [ ] Other *(Please specify)* [ ] : |
| Member of, or affiliated with, the governing body of the Registry? | Yes [ ]  No [ ]  |

 *(If there is more than one, please add table)*

* 1. **Registry Administrative Contact**

**\* For external registries, both the external contact and the Eastern Health contact are required**

|  |  |
| --- | --- |
| Title and Name |  |
| Appointment/Position |  |
| Department & Institution |  |
| Phone |  |
| Email |  |
| Relationship to Eastern Health | None **[ ]**  Current employee **[ ]** Dual Appointment **[ ]** Other *(Please specify)* **[ ] :** |
| Member of, or affiliated with, the governing body of the Registry? | Yes **[ ]**  No **[ ]**  |

*(If there is more than one, please add table)*

* 1. **Eastern Health Clinical Lead/Sponsor**

(In most cases, the Eastern Health Clinical Director for the specialty relevant to the Registry)

|  |  |
| --- | --- |
| Title and Name |  |
| Appointment/Position |  |
| Specialty/Program |  |
| Phone |  |
| Email |  |
| Member of, or affiliated with, the governing body of the Registry? | Yes **[ ]**  No **[ ]**  |

1. **REGISTRY TYPE**

Tick the appropriate box

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| * 1. Is the Registry a Nationally recognised Clinical Quality Registry?
 |  |  |
| * 1. Is the Registry an international Registry?
 |  |  |
| * 1. Is the Registry a Victorian initiative only?
 |  |  |
| * 1. Is the Registry part of the Monash University Clinical Registries Portfolio?
 |  |  |
| * 1. Is the Registry confined to a local cohort of Eastern Health patients only?
 |  |  |
| * 1. Other (please specify):
 |  |  |
| * 1. Are any Eastern Health clinical staff members of, or affiliated with, the governing body of the Registry?
 |  |  |

1. **PARTICIPANT RECORDS**
	1. **Estimated number of participant records to be registered on behalf of Eastern Health per annum:**  \_\_\_\_\_\_\_\_\_
	2. **Participants – Details**

Brief description of target population/participants including their age range (include proposed commencement date of data collection.)

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* 1. **Identifiable Sources of Information. (Please note that data must be de-identified following collection. Only de-identified data can be used for publication purposes.)**

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| --- | --- |
| **Source** | **Information required** |
| *e.g. medical records, collection of biological materials* | *e.g. names, date of birth, medical history, diagnostic test results, treatments and outcomes* |
|  |  |
|  |  |

*(add more rows as required)*

* 1. **Data Collection:**

Is data collection for the Registry likely to continue beyond twelve (12) months? **Yes** **[ ]**  **No**  **[ ]**

If Yes, what is the expected end date of data collection? \_\_\_\_ / \_\_\_\_ / \_\_\_\_

**NOTE:** Collection of data by a Registry is initially approved for a period of 12 months from the date of approval by the Eastern Health Office of Research and Ethics. Continued approval to collect data beyond 12 months will be subject to submission of an annual progress report.

* 1. **Data Format:**
* Review of hard copy or electronic records by Registry staff **Yes** **[ ]**  **No**  **[ ]**
* Provision of a data file from the EH Business Intelligence Unit **Yes** **[ ]**  **No**  **[ ]**

Frequency required? (E.g. Monthly, Quarterly, Yearly)

Specify:

* Provision of tissue samples or other biological materials **Yes** **[ ]**  **No**  **[ ]**

Specify:

* 1. **Minimum Data Set**

Is a minimum data set for the Registry available upon request? **Yes** **[ ]**  **No**  **[ ]**

1. **COLLECTION/USE/DISCLOSURE OF INFORMATION**
	1. **Describe the security arrangements for storage of the Registry information.**

Where will the information (paper and electronic) be stored?

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|  |

Who will have access to the information (paper and electronic)?

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|  |

For what period of time will the Registry information be retained?

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How will the information (paper and electronic) be disposed of at the end of this period?

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How will the privacy of individuals be respected in any publication/report arising from this Registry?

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* 1. **Dissemination of Results (Only de-identifiable data is able to be published)**

Please outline the Registry reporting cycle:

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* 1. **Outline how the Registry will report risk-adjusted outcome analyses to all stakeholders.**

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1. **GOVERNANCE**
	1. **Research Governance**

Has a Research Collaboration Agreement (RCA) or similar been signed

by Eastern Health specifically for participation in this Registry? **Yes** [ ]  **No** [ ]

If No, provide details of any other agreement/ contract in place:

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**Please attach a copy of any relevant agreements with this application.**

* 1. **Clinical Governance**

Specify which Clinical Governance Committee will have oversight for the patient outcomes reported within the Registry, and for addressing any improvements in patient care:

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1. **UNDERTAKING**

By signing and submitting this application, Registry representatives have agreed to the following:

1. All details entered in this application are correct to the best of my/our knowledge.
2. Data collection will only commence once the Registry has been issued with formal approval by the Eastern Health Office of Research and Ethics.
3. The Registry will be conducted in accordance with the protocols and procedures as described within the application and with Eastern Health policies and guidelines.
4. All data collected from or about participants will be de-identified and kept confidential and only unidentifiable data will be published.
5. Research hypotheses arising from the registry information must be treated as a separate research study and therefore must apply for Eastern Health HREC Ethics approval for each study.

Registry representatives are also reminded that:

1. The Registry may only use the data regarding Eastern Health participants for the primary purpose it was collected.
2. Data pertaining to Eastern Health participants must not be released to third parties without appropriate permissions.
3. Eastern Health clinicians may request ad hoc reports from the Registry to support local quality assurance activities, but must seek prior approval by the nominated Clinical Lead accountable for the Registry.

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| --- | --- | --- |
| **SIGNED BY:** |  | **SIGNED BY:** |
| **Registry Clinical Lead** *(Eastern Health contact)* |  | **Eastern Health Clinical Lead/Sponsor** |
| **Signed** |  |  | **Signed** |  |
| **Name** |  |  | **Name** |  |
| **Date** |  |  | **Date** |  |
|  |  |  |
|  |  |  |

***Submit Application and any supporting documents to*** ***ethics@easternhealth.org.au***

The Office of Research and Ethics aims to process applications as soon as possible. If there is a need for urgency, please provide details in your submission email and this will be taken into consideration.