**Statement of principles regarding sample/data access**

* The ENDIA Study has developed a repository of biospecimens and data that may be used as a resource for further expansion of the studies goals, for contributing to our understanding of other disease processes, and for educational purposes. The Study has a responsibility to ensure that the use of samples/data is ethical, purposeful and consistent with the goals of the ENDIA Study.
* Any individual, collaborative group or institution may submit a request for sample/data access in accordance with the defined mechanism.
* In making samples/data available to external collaborators, the ENDIA Study Team is bound by its obligations to Study participants, Human Research Ethics Committees, funding bodies, institutions, government agencies and key stakeholders.
* Requests for ENDIA biospecimens for assay, platform, or method development or beta testing will generally not be appropriate.
* Individuals, collaborative groups and/or institutions accessing samples/data from the ENDIA Study will be bound by the ENDIA Study Publications Policy and will be required to submit publications generated using ENDIA Study materials to the ENDIA Publications Committee.

**Summary of the sample/data access request procedure**

1. An ENDIA Sample/Data Access Concept (ESDAC) Form should be completed and provided to the ENDIA Steering Committee via email: endia@adelaide.edu.au. Applications will be considered as confidential and will not be distributed beyond the ENDIA Study Team.
2. The ESDAC Form will be assigned an ESDAC reference number.
3. The ESDAC Form will be first assessed by three or more members of the Study Team. Applications received by internal Study Team members must be reviewed by investigators of an alternative ENDIA Theme. Data only requests by internal Team members may circumvent the review process if deemed appropriate by a member of the ENDIA Steering Committee Executive or Theme leader.
4. A review of the application will be made within two weeks using the Report of Assessment form. The report will be distributed to all members of the ENDIA Steering Committee for joint discussion and decision at the next meeting of the Steering Committee, held bimonthly. There are three types of outcomes:
	1. Request denied
	2. Request not approved at this time but will be considered in the future
	3. Request approved
5. The Applicant will be informed of the Steering Committee’s decision via telephone.
6. In the case of approval whereby the applicants are members of the **internal** ENDIA Study Team, the applicant will provide evidence of HREC approval for the proposed activities using the HREC Approval Notification Form.
7. In the case of approval whereby the project includes **external** collaborators, external members will be required to sign an ENDIA Study Sample/Data Access Agreement as well as providing evidence of HREC (or international equivalent) approval prior to the samples/data being provided.

The request and approval process is summarised as follows:



Each application must nominate a single lead investigator to whom correspondence will be directed. Please email your completed Concept Form in either Word or PDF format to endia@adelaide.edu.au for consideration by the ENDIA Study Steering Committee.

|  |  |
| --- | --- |
| **Lead investigator name:** | Click here to enter text. |
| **Lead investigator position:** | Click here to enter text. |
| **Lead investigator email:** | Click here to enter text. |
| **Lead investigator telephone (required):** | Click here to enter text. |
| **Lead applicant institution:** | Click here to enter text. |
| **Co-applicants:***Provide contact details for all external co-applicants* | Click here to enter text. |

**Proposed project title:**

|  |
| --- |
| Click here to enter text. |

**Background & rationale for project (approximately 100 words):**

|  |
| --- |
| Click here to enter text. |

**Aims and hypothesis of the project (approximately 100 words):**

|  |
| --- |
| Click here to enter text. |

**Brief research plan (approximately 200 words):**

|  |
| --- |
| Click here to enter text. |

**Expected outcomes of the project and their significance (approximately 100 words):**

|  |
| --- |
| Click here to enter text. |

**Details of samples/data requested**

*Include type, number required, time points required, volume required, etc. where appropriate*

|  |
| --- |
| Click here to enter text. |

**Timelines:**

|  |  |
| --- | --- |
| Date samples/data required: | Click here to enter text. |
| Anticipated completion date of analysis: | Click here to enter text. |
| Anticipated date of publication :  | Click here to enter text. |

**Funding status:**

|  |  |
| --- | --- |
| [ ]  **Funding secured***Provide details of funding body, application ID, and amount available to proposed project including sample transport costs* | Click here to enter text. |
| [ ]  **Requesting access for funding application** *Provide details of funding body, application ID and budget requested for proposed project* | Click here to enter text. |

**Preliminary titles of potential publication(s):**

|  |
| --- |
| Click here to enter text. |

**Has ethical approval been obtained for this project?**

|  |  |
| --- | --- |
| [ ]  **Yes** | [ ]  **No**  |

**Do you require a confidentiality agreement?**

|  |  |
| --- | --- |
| [ ]  **Yes** | [ ]  **No**  |

**Assurances:**

In submitting this Sample/Data Access Concept Form, I/we agree to the following conditions:

* The samples/data requested will only be used for the purposes outlined herein. Any deviation from this proposal, including the stated timelines, must be agreed upon by the ENDIA Study Steering Committee.
* Sample/data will not be passed on or shared with a third party unless agreed upon by the ENDIA Study Steering Committee.
* Requested biospecimens will only be committed to established assays, platforms and/or methods and will not be used for developing novel or beta testing novel assays, platforms and/or methods unless agreed upon by the ENDIA Study Steering Committee.
* Acquiring the relevant HREC/IRB approvals will be the responsibility of the applicant(s) and sample/data access will not be provided until this has been demonstrated to the ENDIA Study Steering Committee.
* By receiving samples/data, I/we acknowledge that we are bound by the ENDIA Study Publications Policy including providing appropriate acknowledgements of the ENDIA Study Team and its sources of funding. I/We will submit publications generated using ENDIA Study materials to the ENDIA Publications Committee for approval prior to journal submission.
* At the completion of the project any remaining biospecimens will be returned to the ENDIA Study biorepository.

|  |  |
| --- | --- |
| Signature of lead investigator: |  |
| Date: | Click here to enter a date. |

*Office use only:*

|  |  |
| --- | --- |
| Submission date: |  |
| Reference number: | ESDAC-\_\_\_\_\_\_-\_\_\_\_\_\_ |
| Outcome: | **[ ]  Approved [ ]  Reconsidered [ ]  Denied**  |
| Outcome date: |  |