**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 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 initially be assessed by the ENDIA Project Management team with input from the Biospecimen Manager and Data Manager to evaluate the feasibility of the request. If further clarification is required, a member of the ENDIA Steering Committee will contact the applicant.
4. Once established as feasible, the ESDAC will be reviewed by three or more members of the Study Team.
5. Reviews of the application will be made within two weeks using the Report of Assessment form. The ENDIA Project Management Team will facilitate any questions or clarifications that assessors may have for the applicant in order to reach a conclusion. Each reviewer will categorise the request as:
	1. Request denied
	2. Request delayed
	3. Request approved

A request may be ranked as “delayed” if, for example, the required data and/or resources cannot be supplied at this time but the application has merit and would be considered again in the future.

1. The reviews will be collated by the Project Management Team. If all outcomes are consistent the request will proceed accordingly. In the case of dissenting reviews, the ESDAC will be tabled for joint discussion and decision at the next scheduled monthly meeting of the Steering Committee.
2. Applications ranked as “Approved” will be reviewed by the ENDIA Data Integrity and Analytics Group (DIAG) to consider all relevant statistical or data access issues. Questions regarding the applicant’s statistical analysis plan may be passed onto the applicant via the ENDIA biostatistician or nominated member of the Steering Committee.
3. Once approved by the DIAG, the applicant will be informed of the decision.
4. Applicants that are **external** to the ENDIA Study Team 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:** |  |
| **Lead investigator position:** |  |
| **Lead investigator email:** |  |
| **Lead investigator telephone (required):** |  |
| **Lead applicant institution:** |  |
| **Co-applicants:***Provide contact details for all external co-applicants* |  |

**Proposed project title:**

|  |
| --- |
|  |

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

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

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

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**Statistical analysis plan (approximately 100 words):**

* *Include name and contact details of any statistician that has been consulted on this project*

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

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**Details of samples/data requested**

* *Include type, number required, time points required, volume required, etc. where appropriate*
* *Include type of participant e.g. islet autoantibody positive, antibody negative, etc.*

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|  |

**Timelines:**

|  |  |
| --- | --- |
| Date samples/data required: |  |
| Anticipated completion date of analysis: |  |

**Funding status:**

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

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

|  |  |
| --- | --- |
| **[ ]  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.

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| --- | --- |
| Signature of lead investigator: |  |
| Date: |  |

*Office use only:*

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