**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, although, a member of the ENDIA Steering Committee should be included as an investigator or sponsor of the proposed project. Please contact the ENDIA Project Management Team via endia@adelaide.edu.au if you are interested in accessing ENDIA samples or data but are not currently collaborating with an ENDIA investigator(s) before submitting an ENDIA Sample/Data Access Concept (ESDAC) Form.
* 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 and Sample Sharing Policies and will be required to submit publications generated using ENDIA Study materials to the ENDIA Publications Committee.
* Following approval of a project via an ENDIA Sample/Data Concept Form, the applicant will gain exclusive access to the requested sample type(s) for analyses in their field of research for 12 months. The purpose of this exclusivity period is to provide the applicant with sufficient time to produce and analyse the data in preparation for publication. After 12 months, the application should report on their progress to the ENDIA Steering Committee. The Steering Committee may choose to extend the period of exclusivity in order to achieve a publication.

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

1. Applicants are recommended to involve an ENDIA biostatistician as part of the team to contribute to the project design and the development of a statistical analysis plan and/or describe the proposed analytical approaches before submitting the ENDIA Sample/Data Access Concept (ESDAC) Form (Schedule 1.1). Applications must also have a member of the ENDIA Steering Committee as an investigator or sponsor of the project.
2. Before completing the ESDAC Form, applicants should contact the Project Management Team via email (endia@adelaide.edu.au) for a feasibility assessment according to sample/data availability. If further clarification is required, a member of the ENDIA Project Management Team or Steering Committee will contact the Applicant.
3. If deemed to be feasible, the Project Management Team will direct the Applicant to complete an ESDAC Form. Submitted ESDAC Forms will be considered as confidential and will not be distributed beyond the ENDIA Study Team.
4. The ESDAC Form will be assigned an ESDAC reference number and circulated for review by three or more members of the Study Team. This may be a member of the ENDIA Steering Committee, or other members of the Study Team who are experts in the area of the proposed project. Applications will be assigned to reviewers by the ENDIA Project Management Team, taking into consideration potential conflicts of interest and frequency of contribution to the review process. External reviewers can be approached under circumstances where the relevant expertise does not exist within the Study Team. External reviewers should be agreed upon by the ENDIA Steering Committee Executive prior to circulation of the ESDAC. A confidentially agreement may be sought if appropriate. Data only requests by internal Team members may be assessed by a single reviewer, who will usually be a member of the Steering Committee Executive or Theme leader. In addition to the ESDAC form, the Project Management Team will provide an assessment of sample availability to assist the reviewers in determining the project’s likelihood of success.
5. The Applicant will be required to make a short presentation about the proposed project at the next scheduled Steering Committee meeting (or next meeting based on their availability). Steering Committee members, including reviewers, will have the opportunity to ask relevant questions of the applicant.
6. Reviewers shall be expected to have read and consider the application prior to the Steering Committee meeting at which the ESDAC is presented. In the week following the meeting, Reviewers should complete a Report of Assessment form taking into account their own views and Steering Committee discussion. Each reviewer will categorise the request as: (a) Request denied, (b) Request delayed, or (c) Request approved
7. 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. The Applicant should be notified of this in writing.
8. The reviews will be collated by the Project Management Team. In case of dissenting reviews, the ESDAC will be forwarded to the ENDIA Steering Committee Executive for discussion and a course of action will be determined.
9. Applicants shall be notified in writing if the application has been declined and the reasoning behind the decision.
10. In the case of approval where the Applicants are members of the internal ENDIA Study Team, the Applicant will provide, or work with the ENDIA Project Management Team to provide, evidence of HREC approval for the proposed activities using the HREC Approval Notification Form (Schedule 1.3)
11. 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 process can be summarised as follows:



Each application must nominate a single lead investigator to whom correspondence will be directed. Please email your completed ESDAC 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. At least one ENDIA Steering Committee member must be included as an applicant or sponsor.* |  |

**Proposed project title:**

|  |
| --- |
|  |

**Background & rationale for project:**

|  |
| --- |
|  |

**Aims and hypothesis of the project:**

|  |
| --- |
|  |

**Brief research plan:**

|  |
| --- |
|  |

**Details of samples/data requested**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Individuals***

|  |  |  |
| --- | --- | --- |
| Donor type | # individuals | Cross-sectional / longitudinal time points |
| Mothers:[ ]  Any[ ]  Nested Case:Control study CASES [ ]  Nested Case:Control study CONTROLS[ ]  Specific FDR proband status[ ]  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| ENDIA Children:[ ]  Any[ ]  Nested Case:Control study CASES [ ]  Nested Case:Control study CONTROLS[ ]  Specific FDR proband status[ ]  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| Fathers:[ ]  Any[ ]  Nested Case:Control study CASES [ ]  Nested Case:Control study CONTROLS[ ]  Specific FDR proband status[ ]  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| Siblings: [ ]  Any[ ]  Nested Case:Control study CASES [ ]  Nested Case:Control study CONTROLS[ ]  Specific FDR proband status[ ]  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |

Other specific donor characteristics (e.g. HLA genotype, FDR proband, breastfeeding status, etc.):***Sample types requested***

|  |  |
| --- | --- |
| Donor type | Specific volume, weight, cell number required per individual per time point |
| [ ]  Serum |  |
| [ ]  Plasma |  |
| [ ]  Peripheral BMC / Cord BMC |  |
| [ ]  Buffy coat |  |
| [ ]  Red blood cells |  |
| [ ]  Stool |  |
| [ ]  Urine |  |
| [ ]  Breastmilk |  |
| [ ]  Vaginal swab |  |
| [ ]  Buccal swab |  |
| [ ]  Tongue swab |  |
| [ ]  Nasal swab |  |
| [ ]  Throat swab |  |
| [ ]  Skin swab |  |
| [ ]  Tooth |  |

Specific sample requirements (e.g. limit on sample processing times, etc.):***Questionnaire outcomes requested***

|  |  |
| --- | --- |
| Data type | Specific data points |
| [ ]  Edinburgh postnatal depression scale (EPDS) |  |
| [ ]  Perceived stress scale (PSS) |  |
| [ ]  Lifestyle questionnaire - pregnancy |  |
| [ ]  Lifestyle questionnaire – infancy (0-3 year) |  |
| [ ]  Lifestyle questionnaire – childhood (3+ years) |  |
| [ ]  Pregnancy physical activity questionnaire (PPAQ) |  |
| [ ]  Basic infant sleep questionnaire (BISQ) |  |
| [ ]  DQES v2 food frequency questionnaire – pregnancy |  |
| [ ]  DQES v2 food frequency questionnaire – lactation |  |
| [ ]  Infant feeding diary |  |
| [ ]  24-hour multi-pass food recall |  |
| [ ]  Australian child eating survey (ACES) |  |

Specific data requirements (e.g. b):***Relevant clinical variables*** [ ]  Date of sample/data collection[ ]  Participant/donor age at sample/data collection[ ]  Gender of participant/donor[ ]  Proband status of participant/donor [ ]  HLA status of participant/donor[ ]  Others (justifications for variables must be provided which specific consideration for this project)**:** |

**Proposed analysis approach:**

* *Include name and contact details of any statistician that has been consulted on this project including the engaged ENDIA biostatistician.*

|  |
| --- |
|  |

**Expected outcomes of the project and their significance:**

|  |
| --- |
|  |

**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.
* Samples should be stored under optimal conditions that will preserve viability. Care should also be taken during handling processes (for example, thawing and re-freezing) to minimise damaging the future integrity of the sample.
* Sample/data will not be passed on or shared with a third party unless agreed upon by the ENDIA Study Steering Committee.
* Electronic ENDIA data, or data generated from ENDIA materials, should be stored on restricted access, password-protected computer and should only accessible by the approved individuals.
* 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: |  |

*Office use only:*

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