**E-Risk Study Concept Paper offline template**

*Note, this is an offline version of this online form:* [*https://redcap.link/ERiskConceptPaperForm*](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fredcap.link%2FERiskConceptPaperForm&data=05%7C02%7Chelen.2.fisher%40kcl.ac.uk%7Cc84a4d2ea196432ef62b08dcbdf30abd%7C8370cf1416f34c16b83c724071654356%7C0%7C0%7C638594098762795017%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=akfcEXDpluPpuu%2BUX2mMNkoZ5HON5uQA%2FI9kJU2bjgE%3D&reserved=0) *You must complete the online form to submit your concept paper to the E-Risk team for consideration.*

Please read the E-Risk data sharing protocol (available here: <https://eriskstudy.com/data-access/>) and then complete all the fields below. If this data request is approved, this form will be posted publicly on this website: <https://sites.duke.edu/moffittcaspiprojects/> alongside previously approved concept papers. If you have any questions, please email us at: eriskstudy@kcl.ac.uk

**1. Collaborating researchers**

***Please note:***

* *Once approved, a formal data use agreement will be required between King’s College London and the university or research organisation that employs any collaborator having access to the data if they are not a member of staff, a student or affiliate of King’s College London. This needs to be signed by both universities/organisations before data access can be granted.*
* *For projects carried out by a student (e.g., MSc/MA, MPhil/PhD, clinical doctorate), the lead applicant should be the student’s supervisor at the same university, and the student should be named as the student collaborator requiring access to the data.*
* *If you have additional collaborators, please name them below and indicate whether they need to have access to the data. It would be common, for instance, for other researchers to see summary results of analyses and act as co-authors on your paper without having access to the data. You will not be permitted to share the dataset except with those indicated in the table as requiring access.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Category** | **Name** | **Email address** | **University / organisation** | **Needs access to data for analysis?***(yes/no)* |
| Applicant *(lead researcher)* |  |  |  |  |
| Student collaborator *(if data is for their dissertation/thesis)* |  |  |  |  |
| E-Risk Sponsor*(if applicant is not an E-Risk investigator)* |  |  |  |  |
| Other collaborator |  |  |  |  |
| Other collaborator |  |  |  |  |
| Other collaborator |  |  |  |  |
| Other collaborator |  |  |  |  |
| Other collaborator |  |  |  |  |
| Other collaborator |  |  |  |  |
| Other collaborator |  |  |  |  |

**2. The project proposal**

***Note:*** *Please provide sufficient detail to enable the committee to review your proposal. Please be as specific as possible about the project aims and analysis methods as once approved this concept paper will be posted publicly and thus will act as a form of pre-registration of your project. Expand boxes as required.*

|  |  |
| --- | --- |
| **Title of project** |  |
| **Background and rationale for project:** *(approx. 300 - 1000 words)* |
| **Project aims / objectives:** |
| **Brief statement of your hypothesis:** |
| **Data analysis methods to be used:** *(approx. 100 - 500 words)* |
| **Significance for theory, research methods, or clinical practice:** |
| **References cited:** |

**3. Expected project outcomes**

***Please note:***

* *The stated end date must be within 24 months of the date when this form is submitted. This end date will form part of the formal data use agreement and on this date you should delete the dataset. Therefore, it must be a realistic date for completion of the project including all analysis, writing a manuscript, review of the manuscript by all collaborators, submission, revisions, and acceptance of a paper for publication.*
* *If you require an extension to the end date of the project, then you should contact Prof Fisher (**helen.2.fisher@kcl.ac.uk**) to discuss this. If you have signed a formal data use agreement, you will need to complete a form to request a licence extension. In some cases, we may also ask you to complete a new concept paper form if there have been substantial changes to the project or a long period of time has elapsed (e.g., greater than a year since the end date of the original project).*
* *If the objective of the project is not a journal publication, please suggest an end date within 12 months instead of 24 months, and state a measurable, concrete outcome. If the objective of the project is a student dissertation, then the expected end date should be the deadline for submission of the dissertation; dissertation projects will only be accepted on agreement that they are strictly not for publication.*

|  |  |
| --- | --- |
| Date form submitted |  |
| End date for the project |  |
| Do you expect to publish your results in a journal? *(yes/no)* |  |
| **If yes**, please provide a provisional list of author names |  |
| **If yes,** please provide a provisional list of journals |  |
| **If no,** please state the expected outcome if the project is successful *(e.g., dissertation, thesis chapter, report)* |  |

1. **List of variables required**

***Please note:***

* *When specifying variables, please be unambiguous. For each variable, specify the name of the measure, twin age, informant, and if you want specific subscales/derived categories (e.g., Depression from interview with twin at age 18; both number of symptoms and DSM-IV diagnosis). Alternatively, for maximum clarity, give actual variable names (e.g., MDESXE18 - MDE Symptom scale - P18 – Elder; DXMDEE18 - Major depressive episode, dsm4 – P18 – Elder).*
* *By default, the dataset will usually include twin and family IDs, the “random” and “true” twin order variables, the cohort the twin is from (1994 or 1995), twin sex, ethnicity and zygosity variables, and family socioeconomic status at age 5. These routine background variables are listed in the table below. If you require further background variables, please specify them in your list.*
* *Access to some parts of the dataset are restricted, namely identifiable data (e.g., postcodes, video recordings, individual-level genotypic and epigenetic data) which will not be shared outside King’s College London, and linked administrative data which is only accessible via the UK Longitudinal Linkage Collaboration’s Trusted Research Environment (this requires a separate formal data access agreement).*

|  |  |
| --- | --- |
| **Variable name** | **Description** |
| *Background variables that will be included by default:* |
| FAMILYID ATWINID BTWINID RORDERP5TORDER RISKS COHORT SAMPSEX ZYGOSITY SETHNICSESWQ35 | Unique family identifierTwin A ID (ex chkdg)Twin B ID (ex chkdg)Random Twin OrderTrue Twin OrderSample GroupsCohortSex of TwinsZygosityEthnicity of TwinsSocial Class Composite |
| *Age 5 variables:* |
|  |  |
| *Age 7 variables:* |
|  |  |
| *Age 10 variables:* |
|  |  |
| *Age 12 variables:* |
|  |  |
| *Age 18 variables:* |
|  |  |
| *Age 26 variables:* |
|  |  |
| *Age 30\* variables:* |
|  |  |
| Are you requesting access to identifiable or linked data? *(yes/no)* |  |
| Which format(s) do you require the data in? *(e.g., .csv, SPSS, Stata, etc)* |  |

 \* Note these variables will not be available until early 2027.

1. **Data security agreement and signature**

Please click in each box to indicate that you will adhere to each of the points listed below.

|  |
| --- |
|[ ]  I am current on Human Subjects Training (CITI (www.citiprogram.org) or equivalent) |
|[ ]  My project is covered by the King’s ethics committee OR I have /will obtain ethical approval from my home institution. |
|[ ]  I will treat all data as “restricted” and store in a secure fashion.My computer or laptop is:a) encrypted (recommended programmes are FileVault2 for Macs, and Bitlocker for Windows machines)b) password-protectedc) configured to lock-out after 15 minutes of inactivity ANDd) has an antivirus client installed as well as being patched regularly. |
|[ ]  I will not "sync" the data to a mobile device. |
|[ ]  In the event that my laptop with data on it is lost, stolen or hacked, I will immediately contact Prof Helen Fisher (helen.2.fisher@kcl.ac.uk), PI of the E-Risk Study.  |
|[ ]  I will not share the data with anyone, including my students or other collaborators not specifically listed on this concept paper as requiring access to the data. |
|[ ]  I will not post data online or submit the data file to a journal for them to post.*Some journals are now requesting the data file as part of the manuscript submission process. Study participants have not given informed consent for unrestricted open access, so we have a managed-access process. Speak to* *Prof* *Helen Fisher (**helen.2.fisher@kcl.ac.uk**) for strategies for achieving compliance with data-sharing policies of journals.* |
|[ ]  I will delete all data files from my computer after the project is complete or by the end date specified on this form, whichever is earliest. Collaborators and students may not take a data file away from the office.*This data remains the property of the Study and cannot be used for further analyses without an approved concept paper for new analyses.* |
|[ ]  I have read the Data Sharing Protocol and agree to follow the instructions. |

By submitting this document, the applicant confirms that they have read and understood their responsibilities as described in the E-Risk data sharing protocol (see: <https://eriskstudy.com/data-access/>) and that they agree to comply with them if this data request is approved. The applicant is asked to type their full name below and select today’s date.

|  |  |
| --- | --- |
| **Type your full name:** |  |
| **Date:** |  |

***Note, you will need to copy and paste the information above into this online form:*** [***https://redcap.link/ERiskConceptPaperForm***](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fredcap.link%2FERiskConceptPaperForm&data=05%7C02%7Chelen.2.fisher%40kcl.ac.uk%7Cc84a4d2ea196432ef62b08dcbdf30abd%7C8370cf1416f34c16b83c724071654356%7C0%7C0%7C638594098762795017%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=akfcEXDpluPpuu%2BUX2mMNkoZ5HON5uQA%2FI9kJU2bjgE%3D&reserved=0) ***in order to submit it to the E-Risk Study team.***

Assuming no additional information or amendments are required to process your form then the E-Risk Data Sharing Committee will aim to provide you with a decision within one month of submission. If approved, we will then securely provide access to the requested data within 1-2 months of a formal data use agreement being signed (if one is required).

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