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For office use…

**Application** **for Access to Genotype Data from ELSA, when linked with other study data.**

*This form should be used only to request links between phenotypes and genotypes. For other application types, please contact the Secretariat for advice on the correct application route.*

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| **1. Project Title** (up to 30 words, plain language) |  |  |

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| **2. Datatypes requested** |  | *Please confirm this application is for* |
|  |  | ELSA genetic data needing linkage with other data from the study. |

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| **3. Plain language summary (PLS)** |
| **Please provide a clear, informative project summary for the committee and public. See METADAC’s** [**PLS guidance notes**](http://www.metadac.ac.uk/files/2017/06/v1.0-Plain-language-guidance-for-METADAC-applications.pdf)**.** 100-150 words. This will be published at www.metadac.ac.uk for successful applications. | |

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| **4. Principal applicant and contact** |  |  |
| *The principal applicant should be a senior academic/researcher/Project PI who can take long term responsibility for the project. Please attach a short CV for the principal applicant (1-2 sides A4)* | | |

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|  |  | **Principal Applicant** | **Contact Person (if different)** |
| Applicant Name |  |  |  |
| Position Held |  |  |  |
| Affiliation |  |  |  |
| Address |  |  |  |
| Email |  |  |  |
| Telephone |  |  |  |
| ORCID ID ( see http://orcid.org/) |  |  |  |

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| **5. Co-applicants** | | |
|  |  | **Name** | | **Affiliation** | **ORCID ID** |
| Co-applicant 1 |  |  | |  |  |
| Co-applicant 2 |  |  | |  |  |
| Co-applicant 3 |  |  | |  |  |
| Co-applicant 4 |  |  | |  |  |
| Co-applicant 5 |  |  | |  |  |

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| **6. Project Details** |
| Key words for application |  |  |
| Proposed Project start Date |  | DD/MM/YYYY: |
| Project finish Date |  | DD/MM/YYYY: |

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| **7. Description of project** |
| **7a: Please state briefly how and why the ELSA study is an appropriate resource for your project.** | |
| **7b: Please provide a concise description of your project**  **See METADAC’s web-site for a summary of the** [**assessment criteria**](http://www.metadac.ac.uk/data-access-committee/application-assessment-criteria/) **and** [**ELSA’s data policy**](http://www.metadac.ac.uk/files/2016/10/ELSA-Genetics-Data-Access_revised_v4_NR.docx)**.**  *Please focus your description on the ELSA resource requested. You may include tables or figures.*  *Please discuss (i) the applicants, (ii) ethico-legal issues including likelihood of generating incidental findings of clinical significance and (iii) the science, using references to the work that informed the design of your study (provide these below).*  *If you are conducting a number of related studies, METADAC recommends that data supporting up to three publications can be requested in one application.*  **This section expands as required. Please use 1-2 sides of A4.** | |
| **7c: Please provide key references for your project (max 10 references).**  *References should show the work on which your project and methodology is based and/or your team’s recent research history.* | |

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| **8. Funding Details** |
| Has the project been peer reviewed? |  | YES / NO |
| When was the project reviewed |  | DD/MM/YYYY: |
| Has the project been funded? |  | YES / NO |
| Name of funding organisation |  |  |
| Final Decision of the funders |  |  |
| Funding start date |  | DD/MM/YYYY: |
| Funding end date |  | DD/MM/YYYY: |

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| **9. DNA** (not available) |
| **10. Samples** (not available) |

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| **11. Genome Wide Genotype Data** |
| *Notes: ELSA genotype data are derived from Illumina Omni 2.5-8 chip.*  *If you have any queries please contact the ELSA Project Manager:* [*n.rogers@ucl.ac.uk*](mailto:genetics@understandingsociety.ac.uk) | | |
| 11.a: Does your project require access to the full data file from the available genome wide scan? |  | *Given the extent of rare variants available in the exome part of the array, the range of other information that it will be possible to link to this file is limited. Limiting your application to the core part of the array will allow for a wider range of phenotype data to be linked.*  Data required:  Full human core exome array YES/NO  Common core variants of the array YES/NO |
| 11.b If YES, please justify your request for the full genome scan |  |  |
| 11.c. If NO, does your project require access to specific SNPs from the Illumina human core exome array? |  | *Please list the SNPs with their Rs number, their chromosome base position Hapmap build, and any potential proxy SNPs in an excel spreadsheet* |

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| **12. Other genotype datatypes** (none currently available) |

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| **13. Other Data** (phenotypes/exposures) |
| *Note: Additional variables may be sensitive and are potentially disclosive. Careful attention is therefore paid to ensuring only necessary data are issued, and all variables must be carefully justified in the context of your analysis. This is particularly important if you request sensitive variables. See* <https://www.elsa-project.ac.uk/availableData> *for information on data in ELSA.* | | |
| Please summarise the variables required and carefully justify these |  | *It is often helpful to state which variables are outcomes, exposures, confounders, or exclusions: this demonstrates that all variables are necessary for the analysis.* |
| Please attach an excel spreadsheet that includes the variable name, description and specific wave(s) for all variables that you require. |  | Spreadsheet attached? YES/NO |
| *Note: Your intentions should be consistent with the Plain Language Summary and the main project description* | | |

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| **14. New variables created by you** |
| Will any new variables be derived  or produced in this project as a result of any data obtained from ELSA |  | YES / NO / unsure  *If NO, you do not need to complete this section. Please proceed directly to question 15.* |
| *Notes* |  | *This information is important, please read the* [ELSA Data Access Policy](http://www.metadac.ac.uk/files/2016/10/ELSA-Genetics-Data-Access_revised_v4_NR.docx) |
| If YES, please describe what variables you expect will be generated by your study |  | *Any derived variable, e.g. an overall activity score, polygenic risk score, imputation* |
| If yes, in order to obtain the data requested in this application, you should return these variables to enhance the Understanding Society resource within 3 months of the end of the agreement. |  | Please confirm you agree to this.  **YES / NO** |

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| **15. Data analysis** |
| Do you have a geneticist to assess potential incidental findings? |  | YES/NO  If YES, state name and affiliation. If NO, state why this is not needed. |
| Do you have a bioinformatician/ statistician who can assist in the analysis of the data requested? |  | YES/NO  If YES, state name and affiliation. If NO, state why this is not needed. |

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| 15b. ‘Incidental findings’. Is it possible that your study will produce incidental findings on genetic variants that could potentially meet the criteria in footnote 1? |  | **YES / NO / unsure**  If no, you do not need to complete this section. Please proceed directly to question 10. |
| *Note: This information is important, please see the* [ELSA Data Access Policy](http://www.metadac.ac.uk/files/2016/10/ELSA-Genetics-Data-Access_revised_v4_NR.docx) *.* | | |
| 15c. If **YES**, please describe what incidental information you believe might be generated by your study. |  |  |
| 15d. If YES, in order to obtain this data requested in this application, you should return these data to ELSA within 3 months of the end of the agreement. |  | Please confirm you agree to this.  **YES / NO** |

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| **16. Data stewardship** |
| *Note: METADAC must be informed immediately of any proposed changes, for example when the Principal Applicant leaves a project or changes institution.* | | |
| Do you agree to obtain prior approval from METADAC of any changes to data stewardship ie. Change of PI, change of institution? |  | *YES/NO* |
| Do you agree to securely destroy your local copy of 1958 data within 2 years of submitting a final report to METADAC, or sooner if you leave the institution where it is held (unless appointing a new data steward, or a data retention plan is agreed)? |  | *YES/NO* |

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| **17. Agreement** |
| **To be completed by the Principal Applicant:** | |
| Can you confirm that you have read the above application and the information contained in it is true to the best of your knowledge? | | YES/NO |
| Do you agree to protect the confidentiality of Research Participants in any research papers, publications or other dissemination activities that you prepare by taking all reasonable care to limit the possibility of identification? | | YES/NO |
| Do you agree not to link or combine the data to other information or archived data available in a way that could re-identify the Research Participants, even if access to that data has been formally granted to you or is freely available without restriction? | | YES/NO |
| Do you understand that data and samples from the ELSA resource cannot be used for commercial purposes? | | YES/NO |
| Are you aware that if you, a member of your group, or your institution were to use these data for such a purpose *without* obtaining prior approval from the METADAC Committee, you will be in breach of the data transfer agreements, and that this might result in you being excluded from using the ELSA resource in the future? | | YES/NO |
| Do you understand that you must not pass on any data or any derived variables or genotypes generated by this application to a third party (i.e. to anybody that is not included in this list of applicants on this project, nor is a direct employee of one of these applicants)?  (This would include any sharing of individual level data with a publically accessible archive). | | YES/NO |
| Are you aware that any third party seeking to use data, samples, or derived variables or genotypes arising from this application must approach the METADAC Committee to obtain access permission of their own? | | YES/NO |
| Any publications resulting from the use of these data must include an acknowledgment to METADAC and the ELSA study, using the acknowledgement at <http://www.metadac.ac.uk/acknowledging-elsa/> and a copy of publications must be provided to ELSA and METADAC. Do you agree to this condition? | | YES/NO |
| Do you understand that if a problem arises involving any misuse of the ELSA data provided for this project - that violates any of the terms and conditions specified by this agreement that you have signed (as the principal applicant) - this will mean that you will be held responsible, and that this might result in you being excluded from using the ELSA resource in the future? | | YES/NO |
| If any new variables will be derived or produced by you or your project team as a result of any data obtained from the ELSA, do you agree to return these variables to ELSA to enhance the resource within 3 months of the end of the agreement, who will then deposit them within 6 months? | | YES/NO |
| If your study produces incidental information on genetic variants that could potentially meet these three criteria:  (i) scientific validity (the genotyping is of adequate quality);  (ii) clinical significance (the disease or condition caused by the genetic variant is potentially serious) , and  (iii) potential benefit i.e. a valid approach exists to prevent or cure the condition/disease of concern and that early knowledge of the genetic risk to which an individual is exposed could enhance the efficacy of that prevention/cure).  do you agree to return these data to ELSA within 3 months of the end of the agreement? | | YES/NO |
| Data security:  Do you agree to make every effort to ensure the data are kept securely, in accordance with current good practice, and to ensure that data are only accessible to the named applicants? | | YES/NO |
| Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

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| **Application submission** |
| *Please attach your application form, CV and variables spreadsheet to an email and send to:-*  Dr Stephanie Roberts  METADAC Committee Secretariat  D2K Group, PEALS  University of Newcastle  .  **Email:** [**metadac@newcastle.ac.uk**](mailto:metadac@newcastle.ac.uk) | |
| *Application deadlines are* ***9.00am UK time****.*  *Deadline dates can be checked at* [*http://www.metadac.ac.uk/data-access-committee/metadac-meeting-dates/*](http://www.metadac.ac.uk/data-access-committee/metadac-meeting-dates/) | |

Footnotes

***1. Criteria for reporting incidental findings to METADAC***

*METADAC policy is that genetic variants that potentially meet the following three criteria must be reported to the METADAC Secretariat.*

(i) scientific validity (the genotyping is of adequate quality);

(ii) clinical significance (the disease or condition caused by the genetic variant is potentially serious) , and

(iii) potential benefit i.e. a valid approach exists to prevent or cure the condition/disease of concern and that early knowledge of the genetic risk to which an individual is exposed could enhance the efficacy of that prevention/cure).

In line with the consents given by participants, there is presently no feedback of incidental findings to participants. However, information is being gathered to inform future policy and strategic decisions in accordance with current best practice (*(Knoppers et al, Eur J Hum Genet 2006;14(11):1170-8)*.