

For office use…

**METADAC Application** **form** **for access to Understanding Society Genotype, Epigenetic and Phenotype Data***This form is for data requests that require links between End User Licence and genetic and/or epigenetic data.*

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

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| **2. Datatypes requested** |  | *Mark all that apply* | |
|  |  | **Genetic data** | **Epigenetic data** |

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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/) |  |  |  |
| Mobile Telephone Number\* |  |  |  |

\* Passwords for encrypted data will be provided via text message to the number given. In the event you are unable to provide a mobile telephone number, passwords will be mailed via postal service.

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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 Understanding Society 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** [**Understanding Society data policy**](http://www.metadac.ac.uk/files/2016/05/UKHLS_DAS_v22-Feb2016.pdf)**.**  *Please focus your description on the Understanding Society 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. Genetic and epigenetic data** |
| *11a. What genetic/epigenetic data are required? (mark with an ‘x’)* |  | **Genetic only  Epigenetic only  Genetic and Epigenetic** |
| *Note: Understanding Society genotype data are derived from the Illumina human core exome array. The datafile has a sex indicator and age band variable.*  *If you have any queries please email the Understanding Society team at genetics@understandingsociety.ac.uk* | | |
| 11b: Does your project require access to the full data file from the available genome wide and epigenetic scan(s)? |  | *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 (please check ONE only)  Full human core exome array  Common core variants of the array |
| 11c: If requesting the full array, please justify your request: |  |  |
| 11d: If not, what specific SNPs and/or gene regions from the Illumina array(s) does your project require? |  | *Please list the SNPs with their Rs number, their chromosome base position Hapmap build, and any potential proxy SNPs in an excel spreadsheet*  Please list specific gene name and chromosome number for specific regions from the epigenetic array in an excel spreadsheet. |

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| **12. Other genetic 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.understandingsociety.ac.uk/documentation> *for information on data in Understanding Society.* | | |
| 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.* |
| Detail the variables required in an attached excel spreadsheet, with the variable name 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 the Understanding Society? |  | YES / NO / unsure  If NO, you do not need to complete this section. Please proceed directly to question 15. |
| *Note: This information is important, please see the* [Understanding Society Data Access Policy Annex 4](http://www.metadac.ac.uk/files/2015/08/USoc-Genetic-Data-Access-Policy-Nov14.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 scores, 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** |
| What managed-access data repository will your arising data be placed with (for example EGA accepts genetic datasets) |  | *Guidance can be obtained from the METADAC Secretariat or Understanding Society.* |

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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* [Understanding Society Data Access Policy Annex 4](http://www.metadac.ac.uk/files/2015/08/USoc-Genetic-Data-Access-Policy-Nov14.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 Understanding Society within 3 months of the end of the agreement. |  | Please confirm you agree to this.  **YES / NO** |

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| **16. Data Security** |
| Every effort should be made to ensure the data are kept securely and only accessible to the named applicants. |  | Please confirm you agree to this  YES / NO |
| Do you agree to obtain prior approval from METADAC of any changes to data stewardship ie. Change of PI, change of institution. |  |  |
| Do you agree to securely destroy your local copy of Understanding Society’s data within 2 years of submitting a final report to METADAC, or sooner if you leave the project (unless appointing a new data steward, or a data retention plan is agreed). |  |  |
| ***Note: Data Security Requirements*** *Data should only be accessible to named users. Files should either have only user Unix read/write access, not group or world access, or project-specific Unix groups should be used for group access that contain only those names authorised to access the data. User IDs within groups should be reviewed at 6 monthly intervals by the applicant. Data kept on laptops or desktop computers should be encrypted when not in active use, either in individual encrypted files or in encrypted directories/partitions. Data should not be held on USB keys or other portable hard drives. Users may be asked to sign an agreement addressing their responsibilities with respect to access to such data. Understanding Society maintains the right to audit IT security arrangements.* | | |

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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 Understanding Society 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 Access Committee, you will be in breach of the data transfer agreements, and that this might result in you being excluded from using the Understanding Society 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 publicly 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 Access 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 to the study, as specified at [*http://www.metadac.ac.uk/understanding-society/acknowledging-ukhls/*](http://www.metadac.ac.uk/understanding-society/acknowledging-ukhls/) . A copy of the publications must be provided to the Understanding Society and to METADAC. Do you agree to this condition? | | YES / NO |
| Do you understand that if a problem arises involving any misuse of the Understanding Society 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 Understanding Society resource and other data governed by METADAC in the future? | | YES / NO |
| Are you aware that your plain language summary will be published on METADAC and Understanding Society websites? | | YES / NO |
| Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

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| **Application submission** |
| *Application deadlines are at* ***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/) | |
| *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) | |

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)*.

**For Understanding Society office use only:**

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| METADAC reference number: |  |
| Date approved by METADAC: |  |
| Date data released: |  |
| Understanding Society Director (signature): |  |