UNDERSTANDING SOCIETY DATA ACCESS STRATEGY

1. OVERVIEW

1.1. Understanding Society is an innovative, world-leading longitudinal data resource designed to address the social issues facing 21st Century Britain. The study offers an unprecedented insight into UK households as they respond to regional, national and international change. Understanding Society is currently the largest study of its kind in the world and will make a major contribution to the UK’s unique and internationally renowned portfolio of longitudinal studies.

1.2. All access to and use of Understanding Society data is governed by the procedures set out in the Data Access Strategy, which seek to be fair, open and transparent.

1.3. The aim of the Data Access Strategy is to ensure that the data produced by Understanding Society is made as widely available as possible to the research community (nationally and internationally), whilst ensuring that sensitive data and/or data which is or may be disclosive of the identities of participants is secure, maintaining the legal and moral responsibility to the study participants and complying with the undertakings given to them (See Annex 1 for more information on participant consents).

1.4. The Understanding Society Data Access Committee (DAC) was established in 2009 to administer and provide oversight for the operation of data access arrangements. The DAC was responsible for developing the Understanding Society Data Access Strategy.

1.5. The DAC was wound up in June 2015. Its responsibilities for regulating access to biological samples, genotype and other related data were handed to a new data access committee covering a range of longitudinal and cohort studies supported by ESRC and other funders, METADAC. Responsibilities for regulating access to other survey and linked data were passed to the Understanding Society Scientific Leadership Team. Oversight and governance of data access arrangements is provided by the Understanding Society Governing Board.

1.6. The Strategy identifies a series of mechanisms to provide access to the data collected by Understanding Society. These procedures apply to all data collected, not just under the main study commissioned by ESRC, but also any co-funded add on studies or data generated by research using Understanding Society data.

1.7. Rules and procedures for access to survey and linked data are set out in Annex 2. Rules and procedures for access to biological samples and genotype data are set out in Annex 3.

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1 Unless otherwise specified, the term ‘data’ when used covers: all information or material gathered during the Study, including blood; DNA, genotypes derived from these samples; and information arising from linkage to administrative data.
1.8. The Strategy builds on existing agreements developed by the ESRC and UK Data Service for accessing data collected by complex longitudinal surveys. It recognises the importance of developing procedures, protocols and standards to support ethical safeguards surrounding data access and the reuse of data for research purposes.

2. DATA ACCESS PRINCIPLES

2.1. The procedures and processes that have been applied to provide access to Understanding Society data derive from the key principles set out below:

i. To maximise the impact of the study, the data produced by Understanding Society is made as widely available as possible to a range of users;

ii. All access to Understanding Society data is governed by the procedures set out in the Data Access Strategy, which aim to be fair, open and transparent. The controls applied are proportionate to potential risks and are designed not to create unnecessary barriers to research;

iii. Understanding Society data (including samples) will be available to all bona fide researchers (whether in universities, government departments, charities or commercial companies), for research that can demonstrate public interest;

iv. The Understanding Society data custodians are the University of Essex;

v. Access requests will be checked to ensure they have had relevant scientific and ethical approval;

vi. The cost of accessing Understanding Society data and samples will be minimised. All applicants will be expected to bear the cost of obtaining data and/or samples;

vii. Users who are not ordinarily resident in the UK are currently not eligible to apply for access to the most sensitive, confidential and/or disclosive data;

viii. Currently all access to survey and related data are managed by the UKDS (see Annex 2); access to genotype only data are managed by EGA, and access to genotype and survey data are scrutinised by the METADAC (See Annex 3).

ix. All requests for access to the biological samples collected by Understanding Society will be governed by the METADAC;

x. As a depletable resource, the use of the biological samples will be carefully controlled, in order to optimise the long-term value of the resource;

xi. Anyone wishing to link administrative to survey data will be required to submit their application to the SLT.

Data Custodianship

2.2. ESRC remains the owner of the property in the Understanding Society database, however as per the Human Tissue Act\(^2\) the samples cannot be ‘owned’. The Understanding Society Scientific Leadership team is the data custodian, responsible for the safekeeping of tissue samples and control of their use, and eventual disposal (if required), all in accordance with legislation and the terms of the consent given by the donor.

Ethical Considerations

2.3. Access to the data is granted in line with the terms of consent (attached at Annex 1) agreed with the study participants. When assessing data access requests by whatever route

consideration is given to whether the proposed research is consistent with undertakings given to Study participants when they gave informed consent.

Commercial Use

2.4. Commercial organisations can apply for access to Understanding Society data and are subject to the standard procedures. For some data the terms of consent may prohibit commercial access. As per any application commercial organisations will be required to demonstrate the public benefits that are likely to flow from the research use. Applicants must confirm that their use of the data is for research purposes and not for commercial exploitation. No organisation, commercial or otherwise should be allowed to gain control or ownership over the Understanding Society resource.

International Access

2.5. International access to Understanding Society data is important and unnecessary barriers should not get in the way of such research. However in some instances procedures for protecting participants’ data from disclosure risk may not be effective outside the UK and access may need to be barred.

Data Security

2.6. ESRC has ultimate responsibility for data security. ESRC considers all issues relating to information security and data protection a high priority and has been working with the Department for Business, Innovation and Skills (BIS), the information commissioner’s Office, the Office for National Statistics (ONS) and the Cabinet Office to addressing these issues. The UK Data Archive, a service provider for the UK Data Service, is ISO27001 compliant and accredited (the information security standard set by the Government). Data security at ISER is managed by the Information Oversight Committee.

Violations of Access Conditions

2.7. Access arrangements will ensure that an appropriate set of penalties are applied should violations of access conditions take place. Penalties can be imposed on users and/or their institutions. Further details for survey and other linked data can be found in Annex 2.
ANNEX 1: UNDERSTANDING SOCIETY CONSENT INFORMATION

Summary of consents in Understanding Society

The overall mechanism of consent is oral. Communication with respondents takes place through advance letters, information leaflets and what is said by the interviewers. Through these means participants are informed of the purpose of the study, how they were selected, the sponsor, how the data will be used, which includes their protection from harm by maintenance of confidentiality of the data. Participants indicate consent by answering questions. Participants are also informed that each year they will be asked to participate.

For study components that go beyond the usual question and answer situation specific consent is sought. Information is conveyed in an information leaflet and/or by the interviewer. Consent is indicated orally or written.

The information leaflets are posted on the website under Fieldwork documents, e.g., http://data.understandingsociety.org.uk/documentation/mainstage/fieldwork-documents.

Information conveyed by interviewers can be found in the questionnaires for relevant waves: http://data.understandingsociety.org.uk/documentation/mainstage/questionnaires.

Each of these areas is organized by wave. Written consent forms are also posted under Fieldwork documents for the appropriate wave.

<table>
<thead>
<tr>
<th>Wave</th>
<th>Study component</th>
<th>Communications</th>
<th>Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>All waves</td>
<td>Basic survey</td>
<td>Advance letters, Information leaflet Participant handbook</td>
<td>Oral</td>
</tr>
<tr>
<td>W1</td>
<td>link educational records of adults age 16 – 24 children age 4 – 15</td>
<td>information leaflet</td>
<td>written</td>
</tr>
<tr>
<td>W1</td>
<td>link health records of adults age 16+, children age 0 – 15</td>
<td>information leaflet</td>
<td>written</td>
</tr>
<tr>
<td>W2</td>
<td>Nurse visit following interview for subset of adults in General Population Sample component</td>
<td>information leaflet</td>
<td>oral (most procedures) written – blood samples for research and/or genetic analysis</td>
</tr>
<tr>
<td>W3</td>
<td>Nurse visit following interview for subset of adults in BHPS sample component</td>
<td>information leaflet</td>
<td>oral (most procedures) written – blood samples for research and/or genetic analysis</td>
</tr>
<tr>
<td>W4</td>
<td>link educational records of adults for those who turned 16 since W1 consent and</td>
<td>information leaflet</td>
<td>written</td>
</tr>
<tr>
<td>Wave</td>
<td>Link</td>
<td>Information</td>
<td>Consent Method</td>
</tr>
<tr>
<td>------</td>
<td>------</td>
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<td>----------------</td>
</tr>
<tr>
<td>W4</td>
<td>Health records adults age 16+, children age 0 – 15. Those who did not consent before and those who turned 16+</td>
<td>Information leaflet</td>
<td>Written</td>
</tr>
<tr>
<td>W4</td>
<td>Benefit records adults age 16+</td>
<td>Information leaflet</td>
<td>Oral</td>
</tr>
<tr>
<td>W5</td>
<td>Higher education statistics agency records. Original sample member or new entrant finished higher education in 1995 or after from a UK institution, continuing sample member received a higher educational qualification since Wave 1.</td>
<td>Information conveyed by interviewer</td>
<td>Oral</td>
</tr>
<tr>
<td>W5</td>
<td>HMRC records adults age 16+</td>
<td>Information leaflet</td>
<td>Oral</td>
</tr>
<tr>
<td>W5</td>
<td>Records from DVLA. Adults who licenced driver with access to car/van for personal use which is registered in UK</td>
<td>Information conveyed by interviewer</td>
<td>Oral</td>
</tr>
</tbody>
</table>

* Rising 16’s asked consents in each subsequent wave
ANNEX 2 DATA ACCESS RULES AND PROCEDURES: SURVEY AND RELATED DATA

1. OVERVIEW

1.1. This document sets out the framework for providing access to all Understanding Society data other than biological samples, genotype and other related data, which are handled by the METADAC. Applications to access survey and other related data are handled by the Understanding Society Scientific Leadership Team (SLT) through the UK Data Service. These procedures operate within the overall framework of the Understanding Society Data Access Strategy.

1.2. There are three categories of Understanding Society data based on the likelihood and potential risk of disclosure. Each have defined access mechanisms;

- The majority of users access data via a standard licence known as an ‘End User Licence’ (EUL). Their application is authorised directly by the UK Data Service;
- Access to more detailed data, which are potentially disclosive of the identities of individuals, households or organisations is provided via a special licence. For a small number of users access to sensitive, confidential and/or disclosive data is provided via ‘Secure Access’ through the UK Data Service. This type of access is only available to persons who are designated as ‘ESRC Accredited Researchers’. Applications for such status are administered by the UK Data Service;

Data Categorisation

1.3. The Understanding Society DAC agreed a set of principles through which the Understanding Society data is categorised, reflecting an assessment of the likelihood and potential impact of disclosure. Data that risk the disclosure of information which could identify individuals, households or organisations with which they are associated will require the highest degree of security and management.

1.4. Understanding Society data falls into one of three categories, which are defined by the likelihood and potential impact of disclosure:

- Impact Level ‘1’: Low impact (non-disclosive data: e.g. most survey responses and digital reports of biological assays and direct physical measurements);
- Impact Level ‘2’ Medium impact (potentially disclosive: e.g. medium level and coarse geographies); for non-UK applicants this category is subdivided into two groups, with the less disclosive subdivision (2a) available to international applicants available on the same terms as for UK applicants, and the more disclosive subdivision (2b) only available if additional safeguards are in place;
- Impact Level ‘3’ High impact (e.g. data with the most detailed geographies).

Table 1 provides examples of data included in each category

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3 http://www.metadac.ac.uk/understanding-society/
4 http://ukdataservice.ac.uk/get-data/secure-access.aspx
Table 1: Examples of data included at different impact levels

<table>
<thead>
<tr>
<th>Impact level</th>
<th>Data included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact Level 1 (EUL)</td>
<td>Content of main interview survey, with some restriction on degree of disaggregation of categories, for example of occupation, industry, country of birth. Top coding of income. Region lowest level of geography.</td>
</tr>
<tr>
<td>Impact Level 2a (Special Licence, available to non-UK users)</td>
<td>Main interview survey data with detailed classifications - Full occupation, industry, country of birth classifications, month as well as year of birth, no top coding of income</td>
</tr>
<tr>
<td></td>
<td>Main interview survey data with intermediate geographies to local authority district, parliamentary constituency, travel to work area</td>
</tr>
<tr>
<td>Impact Level 2b (Special Licence, not available to non-UK users)</td>
<td>Main interview survey data with neighbourhood spatial data; or with Organisation identifiers (e.g. School identifier codes)</td>
</tr>
<tr>
<td>Impact Level 3 (Secure Data Service)</td>
<td>Very fine geographies: postcodes or grid references</td>
</tr>
<tr>
<td></td>
<td>Administrative data linked at individual level (e.g. education data)</td>
</tr>
</tbody>
</table>

The table below shows the how different combinations of data would be classified under this proposal.

<table>
<thead>
<tr>
<th>Main interview survey data with detailed classifications</th>
<th>Intermediate level spatial data</th>
<th>Neighbourhood spatial data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main interview survey data with detailed classifications (2a alone)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intermediate level spatial data (2a alone)</td>
<td>Category 2b</td>
<td></td>
</tr>
<tr>
<td>Neighbourhood spatial data (2b alone)</td>
<td>Category 2b</td>
<td>Category 2b</td>
</tr>
<tr>
<td>Organisation identifier (e.g. school codes) (2b alone)</td>
<td>Category 3</td>
<td>Category 2b</td>
</tr>
</tbody>
</table>

1.5. In general projects are limited to a maximum of three ‘special licence’ datasets due to the increased risk of disclosure through small intersections. However, this is judged on a case by case basis.

**Commercial Use**

1.6. Commercial organisations can apply for access to Understanding Society data and are subject to the standard procedures (outlined in section 1.2 of this Annex). As per any application commercial organisations will be required to demonstrate the public benefits that are likely to flow from the research use. Applicants must confirm that their use of the data is for research
purposes and not for commercial exploitation. No organisation, commercial or otherwise should be allowed to gain control or ownership over the Understanding Society resource.

Data Linkage

1.7. Where consent has been obtained, Understanding Society data may be linked to administrative data (e.g. school and hospital records) and to text, voice and video information. Data linkage will be carried out in secure conditions, to ensure that the owners of the administrative data cannot link data collected in the Survey to the name and address of the person concerned. Therefore any application to link Understanding Society data will be classified as Impact level ‘3’.

1.8. Access procedures for researchers wishing to link the data at individual, organisation and area level will be governed by the conditions of access set out in this Strategy. Where the data owner is not ESRC, approval will be required from the data owner, before any decision is made by the SLT on whether to grant access. The ESRC recognises that Intellectual Property Rights in relation to some data linked to the Study from other sources, such as administrative data from a government department, will remain with the organisation which supplies it and cannot be transferred to the ESRC.

Violations of Access Conditions

1.9. Access arrangements will ensure that an appropriate set of penalties are applied should violations of access conditions take place. Penalties can be imposed on users and/or their institutions. Further details can be found in section 2.6 below.

2. DATA ACCESS PROCEDURES

2.1. Understanding Society data is made available for researchers to undertake their analysis by identifying and requesting data from the UK Data Service.

2.2. Each Impact Level of data has its own access mechanisms. The majority of users will apply to use Impact level ‘1’ data via a standard licence known as an ‘End User Licence’ (EUL). Their application is authorised directly by the UK Data Service. Access to more detailed data, classified as Impact level ‘2’, which are potentially disclosive of the identities of individuals, households or organisations is provided via a special licence. Again this level of access is authorised directly by the UK Data Service after consultation with the SLT. For some users access to Impact level ‘3’ sensitive, confidential and/or disclosive data is provided via ‘Secure Access’ through the UK Data Service. Such applications are reviewed and approved by the SLT.

2.3. Understanding Society biomedical data that are not distinct from the main survey data (measurements collected by the nurse e.g. blood pressure and analytes derived from the blood samples) are covered by standard access procedures. As indicated in paragraph 1.1 access to biological samples and genotype data is regulated by METADAC.

2.4. The arrangements for access to each category of data are outlined below. Penalties for misuse of data under each category are included. Full details of penalties attached to each possible type of misuse are detailed in the UK Data Service Breaches Penalties Policy⁵.

⁵ http://ukdataservice.ac.uk/media/176861/UKDA142_SDS_SecurityBreaches_public.pdf
Impact Level ‘1’: Standard Conditions

Access Agreements

2.5. Users are asked to register with the UK Data Service and agree to the terms of the ‘End User Licence’ (EUL).

Penalties

2.6. Penalties for misuse of the data depend on the severity of misuse but include:
   - suspension of rights for the user to access UK Data Service services for a fixed period or permanently;
   - suspension of the user’s institution’s access to UK Data Service for a fixed period or permanently;
   - suspension of access from all ESRC data services (both individual and institution) for a fixed period or permanently;
   - sanction from future ESRC funding (individual and/or institution) for a fixed period; and
   - whatever penalties may exist in law under the Statistics and Registration Services Act 2007, the Data Protection Act, or any other relevant legislation.

Impact Level ‘2’: Special Licence

Access Agreements

2.7. Potential users are required to register with the UK Data Service and apply to via ‘Special Licence’ for particular datasets for a particular research purpose. Users can request data from UK Data Service in the usual way and will be directed the ‘Special Licence’ forms for completion. The UK Data Service will seek approval for the user and the research from the Understanding Society Scientific Leadership Team, which will act as data custodian under delegated authority from the Governing Board, on behalf of the ESRC as the data owner. Where the data owner is not the ESRC, approval will be sought from the data owner before a decision is made.

2.8. Access agreements for users outside of UK HE sector may be restricted for this level of data depending on the security and institutional arrangements of their host organisation. Decisions will be made on a case by case basis, depending upon information provided in the ‘Special Licence’ application. In most instance non-UK applicants will only have access to category 2a data.

Penalties

2.9. As per Section 2.6 above with all licenced data, penalties will depend on the severity of misuse.
Impact Level ‘3’: Secure Access

Access Agreements

2.10. The Statistics and Registration Services Act 2007\(^6\) widens the potential for access to official statistics by individuals who are designated ‘Approved Researchers’ for a particular usage.

2.11. The ESRC has adopted and extended this model for access to detailed data distributed by the UK Data Service which is not explicitly covered by the Statistics and Registration Services Act 2007 (i.e. data created by academic research units rather than Government Departments), creating a parallel designation of ‘ESRC Accredited Researcher’.

2.12. Users for this level of data access are required to be registered users of the UK Data Service. They will also need to complete the ‘ESRC Accredited Researcher’ approval process, providing details of their intended usage which the SLT, on behalf of the data owners, will use to judge whether secure data are in fact required. Where data ownership is shared or does not sit with ESRC, approval will be sought from the data owner, before a decision is made on whether to grant access.

2.13. On gaining approval, users are required to complete a training session introducing them to the UK Data Service (or its equivalent) and their responsibilities in its use, including information about statistical disclosure control, handling of confidential data, their responsibilities in law and the potential penalties.

2.14. On completion of training, users are asked to sign an ‘Agreement of Terms of Use of the Service’ and will be allocated credentials to access the data securely.

Penalties

2.15. Policies developed by the UK Data Service (or its equivalent) will be applied to the use of Understanding Society data for this level of data access. These include all of the measures listed above.

2.16. Applicants applying to access Understanding Society data who wish to determine whether the data is suitable for the planned research will be able to consult the online documentation or consult the Understanding Society support staff at the University of Essex

https://www.understandingsociety.ac.uk/documentation/help

3. APPLICATION REVIEW PROCESS

3.1. Requests to access data are made to the UK Data Service.

3.2. Applications for requesting access to Impact level ‘2’ or ‘3’ data will be forwarded to the SLT by the UK Data Service. The SLT will determine whether the proposal meets the criteria established by the Committee (see 3.3 below).

\(^6\) http://www.legislation.gov.uk/ukpga/2007/18/contents
3.3. Applications for data are considered by the SLT within 10 working days. Applications are assessed using the following criteria, and in the light of the impact levels outlined above:

1. Has the application been submitted by bona fide researchers who can demonstrate public interest?
2. Does the application violate (or potentially violate) any of the ethical permissions granted to the study or any of the consent forms signed by the participants or their guardians?
3. Does the application run the risk of producing information that may allow individual participants to be identified?
4. Does the application run a significant risk of upsetting or alienating study members or of reducing their willingness to remain as active participants in Understanding Society based research?
5. Does the application address topics that fall within the acknowledged remit of the Understanding Society project, as understood by participants?
6. Does the application demonstrate that ESRC policy regarding deposit of data will be adhered to?

3.4. If access is granted, the data will be made available through UK Data Service under a Secure Access/Special Licence agreement.

3.5. The SLT will review decisions in the case of appeals received from potential users. If the SLT is content with the decisions made it will refer the complaint to the published categorisation principles. A further appeal may be made to the Understanding Society Governing Board. A sub group of the Governing Board will be convened to discuss the appeal. Their decision will be reported to the next Governing Board meeting.

3.6. The Governing Board will also have oversight of the whole process. SLT will report to them at each meeting: numbers of applications in different categories considered, number approved and rejected, any issues arising which suggest the need for a review of the Data Access Strategy. Should the Governing Board consider a substantial review of the Data Access Strategy is required it may initiate a consultation with external experts, but the Board would be responsible for agreeing a revision.

4. DATA RETURN POLICY

4.1. It will be a requirement that any researcher who is approved for access to Understanding Society data and in the process of undertaking their research generate new data, the new data and associated metadata must be offered for deposit to a standard agreed with UK Data Service. Deposit of analysed data will be the responsibility of researchers and penalties may be incurred for failure to adhere to the agreed policy.
ANNEX 3 ACCESS TO GENOTYPE DATA

1. *Understanding Society* has a significant biological component, including direct measures like blood pressure and the collection of biological samples. The study has captured bio-medical assessments on approximately 20,000 adult survey participants and obtained approximately 13,500 biological samples.

2. This Annex describes the process of gaining access to one product of this data collection, the results of genotyping deoxyribonucleic acid (DNA) samples, including data from a genome wide scan using an Illumina human core exome array. Further information about the Illumina human core exome array is available at [http://www.illumina.com/products/humancore_exome_beadchip_kits.ilmn](http://www.illumina.com/products/humancore_exome_beadchip_kits.ilmn). With consent, 10,500 DNA samples have been genotyped. Access to genotype only data are managed by European Genome/Phenome Archive (EGA)⁷, and access to genotype and survey data are scrutinised by the METADAC⁸.

3. The principles guiding access to *Understanding Society* genotype data are those of the overall study expressed in the main Data Access Strategy. There are a small number of variations set out in the paragraphs below.

4. The data should be available to researchers consistent with the terms of consent for the specific data requested. The consent form for blood and DNA collection is appended to this annex. Communications with study participants for the collection of biological samples from which this data derives can be found in the Wave 2 Nurse section of the website for fieldwork documents: [https://www.understandingsociety.ac.uk/documentation/health-assessment](https://www.understandingsociety.ac.uk/documentation/health-assessment).

5. Given the nature of the consents provided by participants, the data are not available for commercial research purposes. ‘Commercial research’ means any research that has, as its primary purpose, the development of products or procedures that may be sold or offered for profit or commercial advantage. Any application from a commercial organisation rather than a charity or not-for-profit would be subject to scrutiny by the METADAC to ensure that there was a demonstrable public benefit arising from the proposed research.

6. Genotype only data are considered Impact Level 2 (IL2) for risk of disclosure, while genotype data combined with other data are considered Impact Level 3 (IL3). For genotype only data, Wellcome Trust Sanger Institute (WTSI) DAC would grant access to them provided the non-UK users meet all the criteria and terms and conditions and provided that the disclosure risk can be managed in a manner equivalent to that for UK based researchers. Genotype-combined with survey data applications would be considered by the METADAC. Only survey data available via the End User Licence would be available to link to genetic data.

7. For disclosure risk and/or QC reasons a number of cases have been removed from the genome wide scan data files before depositing. These include those cases where genetic and reported gender or parentage (where both child-parent have provided DNA) results do not match.

8. Where an application relates to genome wide scan data from the Illumina human core exome array, with the addition of an age band variable but with no other data from the survey, applications should be made to the WTSI DAC. The data at the EGA will include standard variables derived from the genome wide information for example family correlations and the

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⁷ https://www.ebi.ac.uk/ega/studies/EGAS00001001232
⁸ [http://www.metadac.ac.uk/understanding-society/](http://www.metadac.ac.uk/understanding-society/)
first ten principal components. The WTSI DAC has been given delegated responsibility for considering such applications within the framework agreed with the former Understanding Society DAC. If the WTSI has any concerns about an application, it will be referred to the METADAC. Once an application is approved, the WTSI DAC will authorise applicants so they can download the dataset from the EGA.

9. Applications for genome wide scan data linked to other survey data should use the application form on the Understanding Society website. This includes the terms and conditions to which the applicant agrees. Applicants are asked to specify the nature of the proposed research and all data to be used in the project. The METADAC will evaluate the application on the basis of:
   • advice from the METADAC technical support team, which will provide advice on the disclosure risk associated with the application
   • where the METADAC or the technical support team consider appropriate, advice from the relevant experts
   • an assessment of whether the applications meets the criteria set out in section 3.3 of the Data Access Strategy.

10. The evaluation of the proposal will be made by the METADAC within six weeks of its submission. The METADAC Secretariat will inform the applicant of the decision in writing.

11. Where the request involves a combination of genotype data with survey data, the dataset will be supplied by ISER. This will include a small subset of survey data to minimise disclosure risk, and depending on the research question, applicants can request the full genome scan or list the Single Nucleotide Polymorphism (SNPs) required.

12. Once an application has been agreed, any future additions to the dataset (for example, if an additional linked phenotype variable is required) will have to be processed by the METADACTechnical Review Team and must comply with the original application. If the additional request is not deemed to be part of the original proposal, a new application will be required.

13. Each application will generate one data file which will be randomly sorted and given a unique identifier. The data set will not include identifiers shared with the survey data set available from UK Data Service or the genome wide scan data at EGA.

14. Whether a researcher accesses the genome wide scan data alone via EGA or in combination with survey data, they will be a non-negotiable requirement to supply the Understanding Society research data manager with three outputs:
   • any new scientific data (e.g. genotypes, or new variables) created in the project these will be shared with the wider scientific community increasing the value of the resource;
   • notification of all publications using the data;
   • any incidental information on genetic variants identified during the research project that could potentially meet three criteria*:
     • scientific validity (the genotyping is of adequate quality);
     • clinical significance (the disease or condition caused by the genetic variant is potentially serious) , and
     • 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).

Please note researchers are not being asked to investigate clinically relevant findings, but to report them if they are identified during the course of their research.
15. *Understanding Society* has no current plans to share incidental clinically significant findings with respondents. Indeed the informed consent given by respondents, in keeping with most other studies, specifies that ‘*that no personal test results from my DNA will be given to me*’. However, there are discussions within the ethical and scientific communities about what constitutes best practice in this respect, and advice may change in the future making it a requirement to report genetic findings to study participants if they satisfy the above criteria. *Understanding Society*, in common with other studies, has therefore decided to collect information on potentially relevant findings from research groups using the DNA data. It should be emphasised, however, that under no circumstances should researchers attempt to contact participants about potentially clinically relevant findings, this would be done, if there was a change in policy, by the *Understanding Society* study team after retrospectively agreeing new consents with participants or alternative ethically approved processes are agreed.

APPENDIX 1 – TEXT FROM CONSENT FORM FOR BIOLOGICAL SAMPLES

I consent to a qualified nurse taking a sample of my blood on behalf of the Institute for Social and Economic Research/National Centre for Social Research.
I have read and understood the Information for Participants leaflet about the second stage of the survey. The nurse has explained the procedures, and I have had an opportunity to discuss these with him/her.

Initial:
I consent to my blood being taken, stored and used in scientific research. I understand that all blood test results and related information will be coded so I cannot be identified. For purposes of scientific analyses, links to my name will be held separately and securely from any data collected. The sample will not be tested for HIV. I also understand my right to withdraw consent for storing the blood sample.

Initial:
I give my consent for a sample of my DNA to be taken from my blood, stored and used in scientific research.
I understand that:
• the DNA samples and related information will be coded to ensure that my personal identity is not revealed to researchers carrying out scientific analysis
• links to my name will be held separately and securely, for administering the study and data collection
• that no personal test results from my DNA will be given to me
• the data and samples will be owned by the Study and the ESRC. No samples or information will be sold.
• The DNA analyses will not be used for paternity analysis, life insurance, mortgage applications or police records.

I also understand my right to withdraw consent for storing the blood sample.