

National Statistician's Data Ethics Advisory Committee

Guidelines on completing the Application for Ethical Review Form

General guidelines

- 1. The application form should be completed in <u>plain</u> English which is understandable to lay members.
- 2. All abbreviations should be explained the first time they are used. The form should contain sufficient information to ensure a thorough ethical review can take place.
- 3. Please complete the form using Arial or Times New Roman font, size 11. Where necessary, expand text boxes on the form to accommodate answers, but ensure word counts are adhered to where specified.
- 4. Avoid including any references to names except in sections C1 and C2 of the application form
- 5. Where sections are not relevant to your study please mark as N/A.

Basic information

Project title

Please provide a short title, no more than two lines, to describe the project. Please make sure that the title is indicative of the project.

Project start and end date

This section should provide the expected start and end dates of the project. You are encouraged to provide accurate dates but a month—year format would suffice for most projects.

Project sponsor(s)

The **project sponsor** is a term referring to the organisation(s) who are funding the research. In practice, the project sponsor is often the organisation requesting the research.

Project Summary (max. 250 words)

In this section you are asked to provide a short background of the project. Please ensure that you stay within the word limit. Make sure you include the following:

1. the aims of the research. e.g. this research plans to link ONS survey data with administrative data from HMRC to explore wage disparity in different regions of the UK;



- 2. an outline of the datasets used;
- 3. the need for doing this research. e.g. there has been an expressed interest from local authorities to understand how low income households can be supported by national initiatives;
- 4. a summary of the benefits to the public. Please note that the need for the project does not necessarily explain its benefit. e.g. understanding how low income households can be supported by national initiatives will be used to inform local authority initiatives, improve resource and increase public awareness, to support households in need:
- 5. a summary of the project outputs. e.g. the results, methods or tools that this project will produce; and
- 6. any useful background information relevant to the application.

Section A: Project details

A1: Legal Gateways

ONS applicants should seek advice from Legal Services in writing for any data share and use required for the research project. This should be captured clearly in this section.

A2: Ethical Approval

It is very important to specify if the application has been previously reviewed or expected to be reviewed by an ethics committee, or a relevant body with similar responsibilities. If that is the case you will be also required to share what was the outcome of the committee, e.g. approved / rejected and the date of the committee meeting.

A3: Proposed site of research

Please provide information about where the research will take place. This should include detail of where any data linkage and/or data analysis will be conducted, e.g. the ONS Secure Research Service.

A4: Data subjects to be studied

Please mark 'Yes' if your project or research applies methods equally to all subsections of the population. If it does not (i.e. it targets specific groups by age, sex, ethnicity etc.) may 'No' and detail which groups the project or research focuses on and the justification for focusing on those groups.

A5: Research methodology and protocol (max. 500 words)

In this section you should provide some details on the research protocols and type of methodology or procedures you intend on using. You must provide sufficient information so that the National Statistician's Data Ethics Advisory Committee can appreciate exactly what you intend to do and how this will result in you achieving your research aims.

You are expected to present:

 an overview of what datasets are considered and why they are necessary to conduct the research;



- key variables that will be used in these datasets, and a justification for why they are required;
- methods, tools and techniques used and consideration of alternatives; and
- research outputs, sharing arrangements and future access to data.

In general, applicants should clarify why the selected data sources and methods were selected with regards to the public benefit of the research. A consideration of alternatives is always helpful in ensuring that the research has taken into account methods with minimal harm to data subjects.

Transparency is very important when providing ethical scrutiny on a project. A list of variables would allow NSDEC to determine if the proposed data use and linkage complies with its ethical principles. All research outputs, the future use of the data and the methods developed should be promoting the transparency principle.

Example (aggregated variables)

Structure of household: information about the household, for example the type of residence and accommodation, tenure, sleeping rough, communal establishment, household deprivation score, living arrangements and household composition. This information will be used to determine whether data subjects have the same access to social housing and other housing schemes as the wider UK population.

A6: Data Use

In this section you must specify all data you will be using in your project. You should enter the name of the dataset you will be using and the date which the extract relates to, alongside the appropriate row which determines the type of data (Administrative, Big, Survey, Census, Other) and under the relevant column heading which indicates what level the data are (aggregate, identifiable, de-identified personal, anonymised/pseudo anonymised).

Where possible, you should provide a justification for why each variable within each dataset is needed to conduct the research and provide detail as to how it will be used.

Example

If for example you were using identifiable data from the Patient Register extract for 2011, you would complete the table as follows:

Type of data	Data Level Please specify the name of the dataset			
	Aggregate Data	Identifiable Data	De- identified personal data	Anonymised/ pseudo anonymised
Administrative data (please specify, e.g. Patient Register 2011, School Census 2012 etc, in the relevant options adjacent)		Patient Register 2011		
Big Data (please specify e.g. Twitter data, smart meters and mobile phones, in the relevant options adjacent)				



Section B: Assessment against NSDEC ethical principles

B1: Public benefit (Principle 1) (max. 500 words)

This section should detail how the research is beneficial to the public. This should not just focus on for example the improvements made to statistics in terms of accuracy, frequency etc., but also how such improvements are likely to be for the public good, for example through delivery of services.

B2: Confidentiality and informed consent (Principle 2) (max. 500 words) This section should detail all safeguards in place to protect the confidentiality of data subjects in the project. Researchers are encouraged to identify any possible concerns on confidentiality and privacy, and describe how they will be addressed.

Preferably in a second paragraph, describe the data security arrangements that constitute this site secure. In case the research is to be conducted in a site known to us, to limit the time spend filling in the application, you may ask the secretariat for standard text.

This covers the following data security arrangements:

- 1. research in the ONS Secure Research Service;
- 2. research in an accredited/approved processing environment;
- 3. statistical disclosure controls; and
- 4. segregation of duties.

As the last part of this principle, applicants should specify how the consent by data subjects is obtained for this project. This is particularly important in projects involving data subjects. Risks to specific groups who may be particularly vulnerable to disclosure should also be considered within this section.

B3: Risks, technologies, methods and quality (Principle 3) (max. 500 words) If the project suggests the use of new technologies or methods, or a novel use of existing methods, you should explain briefly how any risks will be mitigated. You must ensure that human oversight is maintained throughout the project, and that there are appropriate quality assurance controls in place throughout the project.

B4: Legal compliance (Principle 4) (max. 500 words)

The proposed research project should clearly outline the legal frameworks in place and compliance against these frameworks. This section should identify the relevant legislation to enable the acquisition, processing, analysis, use, sharing and curation of data.

If you are using third party data, you should specify what data you are accessing from a third party and how you will be accessing it. You should ensure that information obtained is in line with Data Protection legislation. This means the full, applicable data protection framework as set out in the Data Protection Act 2018 which encompasses general processing (including the General Data Protection Regulation and the applied GDPR).



ONS applicants should provide written advice from Legal Services outlining the legal gateways under which access is given.

B5: Public engagement (Principle 5) (max. 250 words)

Please detail any public engagement activities (e.g. consultations, focus groups) to identify the views of the public in light of the data use and the perceived benefits of the research project.

B6: Dissemination of findings (Principle 6) (max. 500 words)

Please detail how your project findings will be disseminated. As part of the National Statistician's Data Ethics Advisory Committee's transparency principle, some information relating to your project may be published on the UK Statistics Authority Website.

B7: Future use of products (max. 250 words)

Please detail any intended future uses for products which are created as a result of the project. This may include new or linked datasets, tools and other intellectual property. This section should also detail how users may go about accessing such products, which may involve legal gateways or licenses.

B8: Collaboration and Sponsors

In this section you should provide the names of all parties collaborating in the research. Please avoid using acronyms in this list but make sure you list any acronyms to be used. For each party you should provide details on the agreement enabling this collaboration. This section should make clear the legal gateways required to collect, process and use data for this research project.

Example			
List of Collaborators/Sponsors	Details and relevant documentation relating to collaboration (you may attach copies of relevant documentation)		
HM Revenue and Customs (HMRC)	MoU in place allowing the use of HMRC data for the production of statistics.		
Department of Work and Pensions (DWP)	Formal agreement in place allowing the use of DWP data for feasibility studies.		
Office for National Statistics			



Section C: Responsible owner and applicant details

C1: Responsible Owner

This is the person responsible for the study. The responsible owner will need to sign the declaration, by typing their name or providing a signature (electronic or scanned) as well as the date this application was signed off.

The responsible owner must ensure that ethical standards are maintained throughout the research project life cycle. Their responsibilities include reporting serious and adverse events.

Reporting Serious or Adverse Events

A serious or adverse event is an information loss that could cause harm or distress to individuals and impact an organisation's reputation.

Office for National Statistics

On discovery of the breach or data loss, or if one is suspected, the responsible owner should report the incident immediately to the Data Protection Office (dpo@statistics.gov.uk) and to Legal Services (legal.services@ons.gov.uk) who will then determine whether to refer the matter to the Information Commissioner's Office. The responsible owner should also contact the secretariat of NSDEC to inform them of the incident and to confirm that it has been logged accordingly.

Government Statistical Service

On discovery of an adverse event such as the loss of data, GSS staff should notify the Head of Profession for statistics. The Head of Profession for statistics within the department should inform the National Statistician or the NSDEC secretariat of the breach. Departments should also escalate the event in line with their own organisational data loss management.

Other researchers

Proposals which make use of other approved processors should follow all reporting routes as specified by the approved processor.

C2: Applicant details

If the applicant is the responsible owner then this section can be left blank

The **applicant** is the person completing the application who will liaise with the NSDEC Secretariat during the application review.



Submission of Application and Supporting Documentation

The responsible owner should sign the application form and send it to Data.Ethics@statistics.gov.uk.

The role of NSDEC, and therefore the National Statistician, differs depending on where the research proposal originates from.

- i. **Office for National Statistics:** decisions of NSDEC for ONS projects are definitive unless overruled by the National Statistician, who as Chief Executive of the Authority and ONS, is accountable for their work. In this instance there is no appeals mechanism.
- ii. Government Statistical Service and devolved administrations: any outcome would be advisory to the department(s) concerned and therefore no appeals process would be required.
- iii. **Digital Economy Act (DEA) accredited research:** NSDEC may provide advice on projects from the research community for the DEA Research Accreditation Panel. Accredited researchers may appeal against unfavourable decisions of NSDEC. Appeals should be directed to the Research Accreditation Panel.

NSDEC Outcomes

In reviewing projects NSDEC will advise the National Statistician to:

- i. approve the research;
- ii. approve the research subject to minor revisions. These will be checked for compliance by the Secretariat;
- iii. recommend major revisions to the research. The researcher would need to reconsider the research in light of recommendations made by the committee, and return the application to a future committee meeting; or
- iv. reject the research advising that the research be stopped from proceeding.