



Background:

It is important that researchers do not just consider what can be done with the data, methods, expertise and technology available to them. It is equally important that researchers consider what *should* be done. This ethics self-assessment has been developed to provide a framework to help all researchers to think about the ethics of their research at an early stage and give them confidence that their plans consider/address accepted ethical principles and practices.

This guidance will clarify the workings of the self-assessment tool and has accordingly identified several items across 4 of the 6 principles where close consideration and detail is required. This document will give further detail and guidance as to what is expected when filling out the self-assessment for these slightly more challenging and subjective items.¹

Structure

The self-assessment form consists of 3 main sections:

1. Basic Information
2. Weightings and sensitive research areas
3. Item scoring scales.

This guidance seeks to clarify the logistics of the weighting system as well as explain what is expected regarding the assessment and justifications of a handful of the item scoring scales

Weightings:

Weight levels are provided in the self-assessment for these five characteristics. This measure helps determine the ethical risk of a project.

| | Weight level | Type 1 if applicable |
|---|--------------|----------------------|
| Is this a data linkage project? | 10% | 1 |
| Does the project involve the use of sensitive personal data (under the DPA and GDPR)? | 20% | |
| Does the project involve the use of patient level health data? | 40% | |
| Does the project include data on children or vulnerable adults? | 40% | |
| Data Sources | | |
| Social media | 10% | |
| Rich media sources | 15% | |
| Metadata or Paradata | 5% | |
| Web scraped data | 5% | |
| Big Data (inc. sensor and mobile data) | 5% | |

| Result | |
|--------|---|
| 1.2 | Low risk - project may proceed after confirmation from the Data Ethics team |

In this example, this project scored 1.1 based on the 22 items. However due to the weightings selected, this project's result multiplies by that respective weight(s) thus resulting in 1.2. The more weightings that are selected, the higher the result will be.

¹ General guidance on all 22 items can be found here:

https://uksa.statisticsauthority.gov.uk/wp-content/uploads/2019/05/2019_Self-assessment_guidance_V2.1.pdf

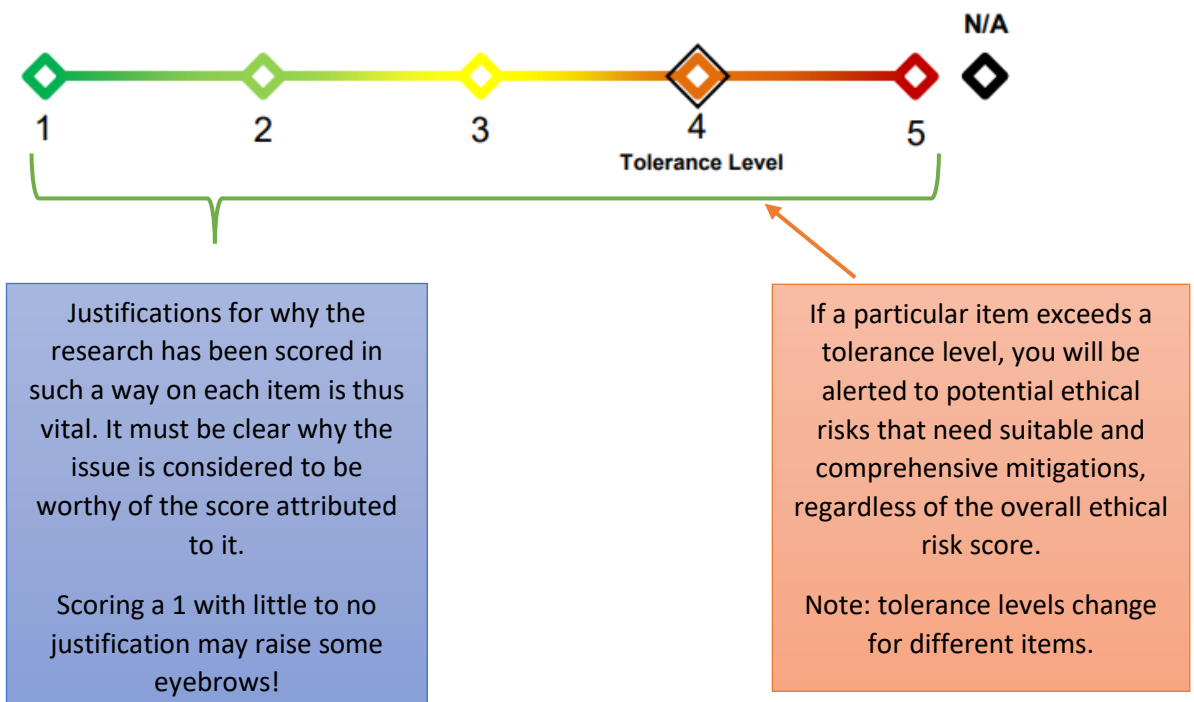
This method of weightings is used due to the binary nature of the issues. For example, you are either doing a data linkage project or you are not. Each issue has a different level of ethical sensitivity and thus must be used when considering the ethical risk of research. The percentage weight for each factor has been carefully considered and is under regular review

Item Scoring Scales

In this section, you are asked to assess your project against 22 items grouped against the six NSDEC ethical principles. For the majority of items, we ask you to respond to each of these items using a five-point Likert type scale.

For some items that require a less granular response, we ask you to respond using a three-point scale. For all items, we also ask you to add a short justification of your selected rating for each item. Where appropriate and justified, some items can be omitted when completing the self-assessment by selecting N/A, but again a short summary of justification is required as to why a response is not applicable.

The average of the rating for all items is a good indicator of the overall ethical risk of the project. However, this could lead to a high ethical risk score being averaged out by the results of the rest of the items. To avoid this, we have introduced tolerances.



Principle 1 - Public Good

Population Coverage

When considering the overall public good of the project, its paramount that who will be affected by the research is assessed. A project that has a narrow focus can prompt many ethical issues:

- The research may disproportionately benefit or disadvantage a particular group
- Thus, the overall public good may be limited. This therefore undermines the overall principle of the public good.
- Focus on a specific group heightens the risk of breaching confidentiality, this is because the risk of re-identification increases.

It is very important to consider who the research affects and to score it accordingly. Research that isn't applicable to the whole population should not be scored '1'. If this is the case, consideration of the risks must be clear and mitigations to circumvent these issues must be shown.

For **population coverage** there is an option to selected N/A if the research is meant to be specific to a particular group. This requires just as much thought and consideration. There must be a justification as to why the research is focused on this specific group in conjunction with the considerations mentioned prior.

| Item | Principle 1 | Score | 1 | 2 | 3 | 4 | 5 | N/A | Score Justification |
|------|---------------------|-------|---|---|---|---|---|-----|---------------------|
| 1 | Public benefit | | | | | | | | |
| 2 | Population coverage | | | | | | | | |
| 3 | Potential harm | | | | | | | | |
| 4 | Biases | | | | | | | | |

Potential Harm

You should consider whether the project and its outputs could cause any potential negative consequences to the public. You should also consider whether the research project could cause any potential harm or distress to any of the individuals involved, including the research participants, the research team, or the research facilitators.
How will this be mitigated?

If there a score of one is given (**negligible harm**), justify why this is so. If there is potential for some harm (scored 2-5 dependant on severity), mitigation must be outlined.

Biases

Throughout the project it is vital that biases are considered, identified and managed

You should consider and outline plans to monitor and manage:

- Potential bias in data sources used
- Potential for bias as a result of the methods employed (assumptions, constraints and limitations)
- Potential for bias in interpreting results and outputs

Biases, regardless of source, can lead to certain groups be disproportionately harmed or benefitted. Thus, it is of paramount importance that you are aware of these biases, and that these are made clear during dissemination so that any policy or influence that occurs as a result of the research is correctly informed.

Principle 2 - Confidentiality and Data Security

Consent

Within this principle, consideration of consent is sometimes overlooked:

Where datasets have been collected using consent as the lawful basis, you must provide assurance that use in this instance is covered by the original statement of consent.

As indicated by the middle response there are instances where consent is not required as the legal basis for processing data. In this case it should be explained what the other legal basis is.

Consent must be well informed, and 'opt in' rather than 'opt out'.

| | Principle 2 | Score | 1 | 2 | 3 | 4 | 5 | N/A | | Score Justification |
|---|-------------------------|-------|---|---|---|---|---|-----|---|---------------------|
| 5 | Direct identification | | | | | | | | - | |
| 6 | Indirect identification | | | | | | | | | |
| 7 | Data Security | | | | | | | | | |
| 8 | Consent | | | | | | | | | |
| 9 | Permitted use of data | | | | | | | | | |

As mentioned above, a score of three suggests:

"Consent has not been obtained, but is not required as a lawful basis"

However, legal research does not always equal ethical research. It is still important to consider whether or not it is ethical for individuals to be given the choice of taking part (hence the score of 3)

Principle 3 – Methods and quality

If your research has some of the issues highlighted below, this may have negative consequences. For example, a study with many assumptions could affect the ability to confidently answer the research question, subsequently meaning any potential public good from the research is unable to be realised.

| | Principle 3 | Score | 1 | 2 | 3 | 4 | 5 | N/A | | Score Justification |
|----|-------------------------------|-------|---|---|---|---|---|-----|--|---------------------|
| 10 | Validity | | | | | | | | | |
| 11 | Standards | | | | | | | | | |
| 12 | Training | | | | | | | | | |
| 13 | Human oversight | | | | | | | | | |
| 14 | New technologies | | | | | | | | | |
| 15 | Potential to realise benefits | | | | | | | | | |

Potential to realise benefits

This item sometimes overlooked by researchers and therefore needs some consideration before completing.

This item is asking you to consider how likely it is that the data/methods used, and outputs produced will actually result in the public benefit. Factors to consider include: quality of the data; the assumptions made; potential risks in achieving the public good; and engagement with relevant stakeholders.

A score of '1' suggests that the "Methods will most likely result in realising the research benefits and fully mitigate any risks". If this is the case with your research, please justify why it **will most likely** occur.

If there isn't this level of confidence with realising the benefits you should score that accordingly.

Principle 5 – Public Views and Engagement

Public views

The wider environment in which researchers operate should always be considered. This does not mean that the public's views must be sought for every project, as this would be disproportionately time and resource consuming, but an overall awareness of public acceptability must be considered. Information from engagement events for similar projects, government initiatives, public polls and literature reviews are reasonable alternatives to large public consultations, focus and expert groups

A score of '1' would suggest the public are widely supportive of the project

Engagement events may result in the realisation that the public's views of the project and/or topic are negative. This must be scored appropriately, and mitigations considered.

| | Principle 5 | Score | 1 | 2 | 3 | 4 | 5 | N/A | | Score Justification |
|----|-------------------|-------|---|---|---|---|---|-----|---|---------------------|
| 18 | Public views | | | | | | | | - | |
| 19 | Public engagement | | | | | | | | | |

A score of '1' would mean that the research involves regular engagement with the public or stakeholders

A score of '5' means that No public engagement has been conducted, or planned, as part of the project

Omit this item when no public engagement is required and can be clearly justified (e.g. for the production of statistics as part of statutory responsibilities; or the same, or a very similar, research project has already completed public consultation or public acceptability testing)

Public engagement is a highly effective technique to help identify and address potential ethical issues in research. It would be disproportionate to conduct direct public engagement for every research project, but it is still vital that you provide evidence that the public views of the way in which data is used in your project have been considered. Appropriate activities may include conducting literature reviews or engaging with relevant stakeholders or experts in the research area and considering the findings of previous/other engagement activity on similar or related topics. It's also important to consider the public's views around the subject/topic area. As set out in the Research Code of Practice and Accreditation Criteria, it is also vital that engagement work takes place to ensure the effective communication and impact of research outputs.