# Ethics Self-Assessment Form for APplications to KMS SDE

## Please complete the sections below:

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| --- |
| Project title: |
|  |
| Applicants, project partners, funder and/or sponsors |
|  |
| Research aims, objectives, or research questions |
|  |
| Data sources (incl. are all sources already available in SDE and anonymised, or are new linkages required) |
|  |
| Special considerations (Max 300 words):   * Will use be made of any protected characteristics (Protected characteristics are defined as age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation, as per the Equality Act 2010) * Does the research focus on those deemed to be at greater risk of disadvantage? (persons that experience a higher risk of poverty, social exclusion, discrimination and violence, including, but not limited to, ethnic minorities, migrants, people with disabilities, isolated elderly people and children) * Does the research focus on a condition which is particularly stigmatised or where people living with the condition are at higher risk of discrimination? * If yes to any of the above, has the research team involved public and patient views in developing their project? |
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## Please complete the following self-assessment according to the guidance given in notes below the table

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| --- | --- | --- | --- |
| Ethical Issue | Risk Descriptors | Project  Risk Level | Applicant Justification of Risk Level |
| Principle 1 (Public Good): The use of data has clear benefits for users and serves the public good | | | |
| Public Benefit | **Low Risk:** This research will provide a significant public good in line with best practice guidance1  **Medium Risk:** Potential to achieve public good which requires further exploration  **High Risk:** Negligible public good that is not in line with best practice guidance1 |  |  |
| Population Coverage2 | **Low Risk:** Public good applicable to entire population  **Medium Risk:** Societal benefits might be limited to certain groups/areas  **High Risk:** Societal benefits will be limited to certain groups/areas |  |  |
| Potential harm3 | **Low Risk:** Negligible harm to anyone involved, including the public  **Medium Risk:** Identified potential harm to anyone involved that can be justified and mitigated against  **High Risk:** Identified potential harm that cannot be mitigated against |  |  |
| Biases4 | **Low Risk:** As yet, bias has not been identified in planned methods and outcomes  **Medium Risk:** As yet, there is potential for bias/bias has been identified, but it can be justified and mitigated against  **High Risk:** As yet, there is potential for bias/bias has been identified, but it cannot be mitigated against |  |  |
| Principle 2 (Confidentiality/Data Security): The data subjects’ identities (whether person or organisation) are protected, information is kept confidential and secure, and the issue of consent is considered appropriately  It is considered that data provision within the SDE largely addresses many of the data security ethical issues (data security, legal basis for data processing, permitted uses of data). However, researchers should show how they have considered the following: | | | |
| Re-identification risk | **Low Risk:** Data provided for the project and/or research outcomes cannot and will not be used to directly or indirectly identify data subjects or specific populations  **Medium Risk:** Don’t know, or unsure if data or research outcomes could be used to directly or indirectly identify data subjects  **High Risk:** Data provided for the project and/or research outcomes could directly or indirectly identify data subjects or specific population groups |  |  |
| Principle 3 (Methods and Quality): The risks and limits of new technologies are considered and there is sufficient human oversight so that methods employed are consistent with recognised standards of integrity and quality | | | |
| Validity | **Low Risk:** Confidence that the methods used, and quality of data will lead to valid conclusions  **Medium Risk:** There is limited confidence/it is unsure whether the methods used, and quality of data will lead to valid conclusions  **High Risk:** Potential that methods used, and quality of data may/will lead to invalid conclusions |  |  |
| Training and Accreditation | **Low Risk:** Researchers are appropriately trained and accredited to recognised standards  **Medium Risk:** Researchers are trained and accredited but have limited experience in particular research area  **High Risk:** Researchers are trained but there is limited assurance in training that relates to this research |  |  |
| Risks with novel software, technologies and automation | **Low Risk:** Research utilises well established methods and technologies with expert human oversight  **Medium Risk:** Methods and tools may be tried, but are still novel or automated, with limited expert oversight  **High Risk:** Research based on untested, automated, or opaque processes with minimal human oversight |  |  |
| Methods are appropriate to generate knowledge to achieve aims | **Low Risk:** Methods and quality of data will most likely result in realising the research benefits and fully mitigate any risks  **Medium Risk:** There is limited confidence/it is unsure whether the methods and quality of data will result in realising research benefits or mitigate risks  **High Risk:** Methods and quality of data have little/no potential to result in realising research benefits or mitigate risks |  |  |
| Principle 4 (Legal Compliance): Data used and methods employed are consistent with legal requirements such as Data Protection Legislation, the Human Rights Act 1998, the Statistics and Registration Service Act 2007 and the common law duty of confidence  It is considered that data provision within the SDE following approval procedures ensures the research is legally compliant. | | | |
| Principle 5 (Public Views and Engagement): The views of the public are considered in light of the data used and the perceived benefits of the research | | | |
| Public views | **Low Risk:** The public is widely supportive of the project aim and method  **Medium Risk:** There is limited support of the project aim and methods from the public  **High Risk:** The public’s views of the project aims, and method are negative or unknown |  |  |
| Public engagement5 | **Low Risk:** The research involves regular engagement with the public and/or stakeholders  **Medium Risk:** The research involves some engagement, though it is not regular throughout the research project  **High Risk:** No public engagement has been conducted, or planned, as part of the project |  |  |
| Principle 6 (Transparency): The access, use and sharing of data is transparent, and is communicated clearly and accessibly to the public | | | |
| Public access to outcomes | **Low Risk:** Research outcomes are, or will be, openly available to the public  **Medium Risk:** Don’t know, or unsure if research outcomes will be openly available to the public  **High Risk:** Research outcomes are not, or will not be, openly available to the public |  |  |
| Sharing of methods and tools6 | **Low Risk:** Both methods and/or tools are, or will be, made widely available to the public  **Medium Risk:** Don’t know, or unsure if methods and tools will be available to the public  **High Risk:** Both methods and tools are not, or will not be, made widely available to the public, or will only be shared internally |  |  |

### Notes:

1) Please refer to the [Research Code of Practice and Accreditation Criteria](https://www.gov.uk/government/consultations/digital-economy-act-part-5-data-sharing-codes-and-regulations/research-code-of-practice-and-accreditation-criteria), clause 33.1: The research project must be in the public interest.

*The Act makes it a condition of the disclosure of data that the research for which the data is disclosed is in the public interest. For the purposes of accrediting research projects the Authority interprets public interest in the same way as ‘public good’, as set out in the Statistics and Registration Service Act 2007. To secure accreditation, the primary purpose of a research project must therefore be to serve the public interest in one or more of the following ways, to:*

* *provide an evidence base for public policy decision-making;*
* *provide an evidence base for public service delivery;*
* *provide an evidence base for decisions which are likely to significantly benefit the economy, society or quality of life of people in the UK, UK nationals or people born in the UK now living abroad;*
* *replicate, validate, challenge or review existing research and proposed research publications, including official statistics;*
* *significantly extend understanding of social or economic trends or events by improving knowledge or challenging widely accepted analyses; and/or,*
* *improve the quality, coverage or presentation of existing research, including official or National Statistics.*

2) Omit this item if the scope of the research is specific to a particular group. However, you should justify why the research is focused on that group, and whether this, or other groups, might be adversely affected by this research.

3) You should consider whether the project could cause any potential negative consequences to the public, and whether these are proportionate to the proposed public benefits of the project; involvement of patients and people with lived experience in the project development will help to elicit any potential negative consequences. Where appropriate, you should also consider whether the activities involved with conducting the research project could cause potential harm or distress to *any* of the individuals involved, including the research participants, the research team, or the research facilitators.

4) Identifying and managing bias is essential in research and, to ensure its integrity, it is important that you consider:

* the data sources used and most importantly how these are produced;
* the effect of researcher or observation bias throughout the lifecycle of the project;
* the methods and algorithms employed, their assumptions and constraints; and
* the outcomes of your research and how your research is presented.

5) 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 if the same, or a very similar, research project has already completed public consultation or public acceptability testing)

6) There are some cases where researchers may not be able to share these tools and methods: Firstly, when reverse engineering the tools or method could compromise the confidentiality of the statistical outputs produced; and secondly, when there is a legal agreement in place that prevents us from doing so, for example tools and methods are produced in partnership with a third party which retains intellectual property rights. Omit this item in these circumstances.

### For further guidance please see:

<https://uksa.statisticsauthority.gov.uk/publication/guidelines-on-using-the-ethics-self-assessment-process/>

### For Data Ethics Group:

A diagram of a graph

Description automatically generated with medium confidence