

UKMED Ethical Approval

Guidance for Researchers

1. Purpose

This document sets out guidance for researchers seeking to use the UK Medical Education Database (UKMED). It outlines the ethical considerations to be addressed prior to submitting an application.

2. Scope

This policy applies to all researchers applying to access and use UKMED data for research purposes. It is relevant for all projects using data that may fall under the definitions of *anonymised* or *pseudonymised* information as defined by the UK General Data Protection Regulation (UK GDPR).

3. Policy Statement

The UKMED is committed to supporting ethical research practices as well as ensuring broader compliance with data protection law. Researchers must seek a favourable ethical opinion (or approval), or confirmation that ethical approval is not required, from the appropriate local committee for any research project. They will need to provide proof of their approval or exemption to the UKMED, ideally as part of the initial application. We will need this proof before our team start building the project's data extract. Researchers will be reminded of this when meeting the GMC to discuss their data specification.

4. Definitions

- **Anonymised Data:** Data that does not relate to an identified or identifiable individual, whether alone or in combination with other data. According to the Information Commissioner's Office (ICO), such data are not considered personal data. For example, data that has been entirely aggregated and small numbers suppressed would be regarded as fully anonymised.
- **Pseudonymised Data:** Data that have been processed to prevent identification without additional information. However, it remains personal data under UK GDPR, as identification is possible when combined with other information held separately, for example, the GMC's public Medical Register. Row by row data is likely to be

pseudonymous and is likely to require both a Data sharing agreement (DSA) and ethics approval.

5. Ethical Approval Requirements

5.1 Anonymised Data

- Data are only considered anonymised if they cannot identify a living individual on their own or in combination with other sources.
- Generally, ethics approval is not required where data are fully anonymised and no personal data are being processed. However, researchers should seek confirmation from their ethics committee on their approach to anonymised data.

5.2 Pseudonymised Data

- Due to the structure of UKMED data and the way it is typically used in research, most projects will involve pseudonymised data.
- A favourable ethics opinion ('approval') is likely to be required for any research involving pseudonymised data. Some ethics committees have viewed UKMED projects with pseudonymised data as not requiring a full review process and were able to fast-track approval.
- Researchers must obtain a favourable opinion from a recognised Research Ethics Committee (REC).
- Evidence of ethics approval (or 'favourable opinion') must be submitted to the UKMED before data access is granted.

6. Additional Safeguards

Where pseudonymised data are used, the UKMED will require:

- A Data Sharing Agreement (DSA) outlining the responsibilities of both parties.
- Assurance that appropriate technical and organisational measures are in place to protect the data.
- Confirmation that the research complies with all relevant legal, regulatory, institutional ethical standards, and UKMED approval process conditions.

7. Responsibilities of Researchers

Researchers are responsible for:

- Assessing your proposed dataset for the potential of re-identification. Are the data anonymous or pseudonymous? Determining whether ethical approval is required based on the data classification and advice from a REC.
- Obtaining and submitting evidence of ethical approval if applicable.

- Adhering to all data protection and confidentiality requirements as outlined in UKMED policies and UK GDPR.

8. Procedures

1. Data Assessment

Researchers must evaluate the identifiability of their proposed dataset, considering the context in which it will be used.

2. Classification

Determine whether the dataset is anonymised or pseudonymised. The [UKMED data dictionary](#) may assist with this.

3. Ethics Approval

- Apply to an appropriate Research Ethics Committee for exemption or a favourable ethical opinion ('approval').
- Submit the approval or exemption advice documentation to UKMED.

4. Data Access

Upon acceptance of ethics documentation and completion of any additional agreements (e.g., DSA), researchers may proceed with the project.

9. Contact and Support

Researchers who require further clarification or support in assessing their data or navigating the ethics approval process are encouraged to contact:

General enquires about ethical approval: the MSC UKMED team

Email: info@ukmed.ac.uk

Specific enquiries about the data held in UKMED in relation to ethical approval: the GMC UKMED team

Email: ukmed@gmc-uk.org

10. Review

This policy will be reviewed annually or in response to changes in legislation or UKMED governance procedures.