Process for completing UKMED research

Version 3 – December 2016

Note on Version 3

1 Version 3 of this document has been drafted to reflect the proposed inclusion of exam data from the Medical Royal Colleges and Faculties. It has been shared with colleges to inform their review of the new proposal.

2 Amendments have been made to paragraphs 19, 20, 50 and 51 to ensure the involvement of colleges in requests involving exam data.

Introduction

3 This document sets out the process for requests for de-identified linked data from the UK Medical Education Database (UKMED) and criteria for assessing these applications.

4 Versions of this document were reviewed by the UKMED Development Group (Renamed in December 2016 UKMED Advisory Board) on 19 June and the 15 October 2015.
Scope of process

5 This process applies if the applicant wishes to use a research dataset only available from UKMED, because the proposed dataset contains data linked from multiple sources that contribute to UKMED. For instance the proposed data come from UKCAT*, GAMSAT, UKFPO† and the GMC‡.

6 This process does not need to apply if an individual applicant only wishes to access data from one organisation that contributes to UKMED. For instance if only GMC data are required for research the applicant could apply directly to the GMC and the GMC’s own processes would apply. Equally, if the applicant only wished for access to UKCAT data; they could apply directly to UKCAT.

* UKCAT- the UK Clinical Aptitude Test see http://www.ukcat.ac.uk/
† Data from Foundation Programme application system https://www.oriel.nhs.uk/Web/, prior to 2016 from Foundation Programme Application System (FPAS).
‡ The GMC contributes data from a number of sources, including data purchased from HESA (Higher Education Statistics Agency see https://www.hesa.ac.uk/) which will be included in every extract as it is used to define the cohort.
Who can apply for a dataset from the UK Medical Education Database?

7 The application process will be open to all those who can complete an application and who would be in a position to satisfy the terms of the data sharing agreement with the GMC as data controller.

8 All organisations contributing data will follow this process for access to linked UKMED datasets.

9 Previous applicants who have received data from UKMED must have demonstrated compliance with the earlier contract and delivery of the planned outputs e.g. a peer review article.

10 The data are for research purposes only and cannot be used to make decisions about individual data subjects.

Application process

Stage 1 – prior to completing an application form

Ethics approval for research

11 Researchers applying for data will be required to demonstrate that the institution of the lead researcher has granted ethics approval or that their proposed study is exempt from the requirement to obtain ethics permission.

12 UK medical schools agreed that all approved applications for research projects using data exclusively held in the UKMED would meet the criteria for a blanket exemption from the need to apply for ethics approval that would be recognised by ethics committees relevant to the UK medical schools.
Funding for UKMED Research

13 Applicants will be expected to demonstrate that funding and/or staff time has been committed to the research or that a relevant research grant has been initiated.

14 No data extracts will be prepared or shared until funding and/or other resources have been secured.

Stage 2 completing an application form

15 Prospective research applicants should complete a standardised application form (illustrative example in Appendix A) containing details about their research question, methods and researchers who will be expected to use the data requested. The online application form can be accessed by logging in on the UKMED website. It has to be submitted through the website.

16 The closing date/s for submitting completed applications seeking approval from a given meeting of the UKMED Advisory Board will be published in advance on the UKMED website.

Stage 3 – review of application form

17 The UKMED Research Subgroup will assess the completed applications assessment against the criteria in Table 2. Members will be able to abstain from scoring a domain if they do not have the expertise pertinent to the specific case.

Table 2 Scoring for UKMED Research Applications

<table>
<thead>
<tr>
<th>Domain</th>
<th>Unacceptable 0</th>
<th>Uncertain – may be acceptable with further clarification 1</th>
<th>Acceptable 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Question</td>
<td>Aims or question not clear. Question appears irrelevant to policy or practice.</td>
<td>Question is poorly defined or uncertain as to whether it is likely to impact on policy or practice if answered. More information or clarification may be required.</td>
<td>Question if answered has significant implications for policy or practice in medical education. The research</td>
</tr>
<tr>
<td>Domain</td>
<td>Unacceptable 0</td>
<td>Uncertain – may be acceptable with further clarification 1</td>
<td>Acceptable 2</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>----------------</td>
<td>------------------------------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>question is original and is not answered in the existing literature.</td>
<td></td>
</tr>
<tr>
<td>Data fields requested</td>
<td>The data requested is not contained in the UKMED.</td>
<td>The data requested is within the database but does not appear capable of answering the research question identified.</td>
<td>The data requested is contained within the UKMED and is well linked to the research question.</td>
</tr>
<tr>
<td>Proposed Methodology</td>
<td>Methods not appropriate to addressing research aims or question.</td>
<td>Methods may seem outdated, over simplistic or not well adapted to nature of data.</td>
<td>Methodology takes into account the nature of and type of data available and is suitable to address the research question.</td>
</tr>
<tr>
<td>Analysis</td>
<td>Analysis not appropriate to addressing research aims or question.</td>
<td>Analysis may seem outdated, over simplistic or not well adapted to nature of data.</td>
<td>Analysis takes into account the nature of and type of data available and is suitable to address the research question.</td>
</tr>
<tr>
<td>Evidence of planned output/use</td>
<td>No statement of intended use</td>
<td>Intended uses unclear.</td>
<td>There is a clear statement on the intended outputs which may include publication in a peer-reviewed journal, publication on an organisation’s website, reports that are evaluations of a service rather than research, or publication as a</td>
</tr>
<tr>
<td>Domain</td>
<td>Unacceptable</td>
<td>Uncertain – may be acceptable with further clarification</td>
<td>Acceptable</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------</td>
<td>----------------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td></td>
<td>Ph.D. thesis.</td>
</tr>
<tr>
<td>Team</td>
<td>Team is not plausible with little evidence of relevant skills or track record. There is no governance structure defined or there is indication that it may not be accountable.</td>
<td>Team may have obvious skills gaps or limited relevant research track record. Governance structure is outlined, but is not very clear.</td>
<td>Proposed team members have a good track record in related research and are likely to have the skills to employ the proposed methodology and manage data issues. Governance structure is described in a clear and accountable way.</td>
</tr>
<tr>
<td>Evidence of Support</td>
<td>No explicit plan for how staff time or other resources will be made available to complete the analysis in a timely manner.</td>
<td>Plan for obtaining funding outlined but not guaranteed. Internal institutional support for staff time may be available.</td>
<td>A source of funding has been identified and obtained. This is likely to be sufficient to cover the costs of the work.</td>
</tr>
</tbody>
</table>

18 The UKMED Research Subgroup members will complete an initial assessment of each application independently. This would be followed by a discussion during the meeting of the Research Subgroup.

19 When a request includes data pertaining to one or more medical royal college or faculty (college) exams, each college involved will be asked to review the application using the sub group’s criteria in Table 2. Colleges may nominate whoever is best qualified to comment on their behalf. Colleges are not obliged to comment.

20 A representative of colleges will be invited to attend in person or via telephone conference the relevant section of the Research Subgroup’s meeting to discuss the proposal. Attendance is not obligatory.
The Research Subgroup will provide an assessment of the proposal for the UKMED Advisory Board against all domains, summarising; the quality of the submission, the potential outcomes of the research and benefits to medical education.

The UKMED Advisory Board will consider the report from the Subgroup and provide advice to the GMC on whether or not the application should be supported and, if not why and what if any feedback should be given to the applicant(s).

UKMED Advisory Board members have committed to support research proposals that have academic merit, even if the possible outcomes may be unfavourable for data contributors or have findings that could be considered controversial.

In case of approved applications, the title, summary and contact details of the lead researcher as recorded on the application form will be published on the UKMED website.

Under most circumstances applications that are approved at the same date will receive their data extracts at the same time.

In the event of there being more requests than it is possible to resource the GMC will work with the UKMED contributors with updates to the UKMED Advisory Board to develop a prioritisation approach.

Stage 4 - Finalising the data specification

Once approved the researcher would work with the GMC’s UKMED Data analyst to complete a final specification of the dataset to be used in the research, this specification will be included in the data sharing agreement.

Stage 5 - Data sharing agreement/contract- GMC Data Controller

Once the specification is finalised the GMC as Data Controller will issue a Data Sharing Agreement, a template Data Sharing Agreement is in Appendix B. This will contractually restrict the researcher’s use of the data to that required for the completion of the research outlined in their approved proposal. It is important to note that the data cannot be used to support measures or decisions with respect to
particular individuals, and cannot be processed in such a way that substantial damage or substantial distress is, or is likely to be, caused to any data subject*

29 The GMC will produce the extract for the study to the required specification, ensuring that the methodology of production is documented.

Stage 6 - De-identification of the data set

30 When providing row by row data, individual doctors will be pseudonymised. Each GMC Reference number contained within the dataset will be replaced by a unique study code. If the dataset contains multiple records with the same GMC number, these records will have the same unique study code. The unique study code will consist of a concatenation of the project code assigned on approval and a consecutive number. The GMC will hold a table that maps GMC numbers to study codes to allow re-identification in the event of the data being queried. Study codes will only be used for one study. This table will only be accessible to analysts working on the UKMED project.

31 The GMC will ensure that individuals cannot be identified using a combination of demographic variables using data minimisation technique such as by applying the concept of K-anonymity. This is satisfied if $K > 1$ for each combination of quasi-identifiers – gender, age, medical school and so forth†. To achieve this it may be the case that some values will be recoded into broader categorisations. The GMC will minimise any reduction in utility by, where possible, only recoding variables that are not explicitly an object of the research proposal. If other techniques are used these will be outlined.

32 On completion of the project the GMC as Data Controller will take responsibility for the secure archiving of relevant analysis files for a period of five years, including a copy of the extract provided.


**Stage 7 – Software arrangements and configuring the safe haven**

33 Researchers will be completing their analysis in the University of Dundee’s Health Informatics Centre (HIC) Safe Haven*

34 Researchers will complete a HIC/GMC Data User Agreement – please see Appendix. C. Note that researchers will need an authorised signatory from their organisation. The GMC will countersign this agreement.

35 Researchers will need to complete a short course on Data Protection before accessing the Safe Haven and provide evidence of completion to HIC. The course “Research Data and Confidentiality” can be found at: http://byglearning.co.uk/mrcrsc-lms/course/category.php?id=1.

36 Researchers will be remotely logging onto a secure server located within HIC to access the data and perform analysis, without being able to copy or remove the data from the secure central server. All the common tools required for the analysis (see list below) are provided for use within this environment and this server can be accessed securely from anywhere.

37 The remote-access Safe Haven utilises a VMware secure environment. In this model data are no longer released externally to researchers for analysis on their own computers but placed on a server at HIC by the GMC, within a secure IT environment, where the researcher is given secure remote access to analyse it. Researchers will need to install the VMware client on their machine or access via http to use the safe haven†.

38 The GMC supply the data to HIC and GMC will be responsible for all queries regarding the data. Researchers will have a named point of contact at the GMC for this purpose. The GMC will transfer files to HIC via a secure file transfer. Within 48 hours HIC will transfer these files to the safe haven environment (except during the 2 week Christmas/New Year period when there will be no Safe Haven support available).

39 Previously written customised code/syntax, libraries of reference data and so forth can be imported once approved by the GMC.

40 HIC is responsible for managing access to the safe haven and working with the researchers to ensure the required software is available. The GMC is responsible for answering any queries on the data supplied.

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* https://medicine.dundee.ac.uk/sites/medicine.dundee.ac.uk/files/Safe%20haven%20User%20Guide.pdf

† https://medicine.dundee.ac.uk/sites/medicine.dundee.ac.uk/files/Safe%20haven%20User%20Guide.pdf
Arrangements for the software depend upon the software required and the nature of the license held by the researcher as detailed in Table 3 below.

All software within the Safe Haven is licenced for academic research only. If the researcher is working on a commercially funded project additional fees will apply.

If a researcher wants to use a different research application to those listed in Table 3 they will need to speak with HIC to check that the safe haven environment can support the software. Some packages may not work correctly in the safe haven environment so this needs to be looked at on a case by case basis. It is important to note that the safe haven is Windows 7 based and Linux or UNIX applications are not supported.

For software that is not included as standard and where HIC Safe Haven can support it, researchers must buy the necessary licence along with the software media (to allow installation) (see table 3 for exceptions for SAS, SPSS and STATA) and pay HIC a £250 installation fee per install.

### Table 3 Software arrangements

<table>
<thead>
<tr>
<th>Software vendor</th>
<th>Product</th>
<th>Version</th>
<th>License arrangements</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBM</td>
<td>SPSS Statistics Premium 22</td>
<td>Researchers must have a comparable (in terms of version and modules) existing site wide academic licence. Users must be academics working for a recognised academic institution. Commercial projects, even when resourced by academic staff, are NOT covered by HIC’s academic licencing agreements. Users would need to buy their own commercial licence. The licence must relate to the same or higher version of the software to those listed above. Researcher must supply HIC with proof of the version of a site wide existing academic licence from their own</td>
<td></td>
</tr>
<tr>
<td>Software vendor</td>
<td>Product</td>
<td>Version</td>
<td>License arrangements</td>
</tr>
<tr>
<td>----------------</td>
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</tr>
<tr>
<td></td>
<td>Revolution R</td>
<td>Revolution R Open 3.2.2 (Community Edition)</td>
<td>3.2.2</td>
</tr>
<tr>
<td>RStudio</td>
<td>R Studio Desktop (Open source edition)</td>
<td>0.99.473</td>
<td>Included as standard (for academics only). Users must be academics working for a recognised academic institution. Commercial projects, even when resourced by academic staff, are NOT covered by HIC’s academic licencing agreements. Users would need to buy their own commercial licence.</td>
</tr>
<tr>
<td>SAS</td>
<td>SAS</td>
<td>9.4 TS Level 1M2 X64_7PRO</td>
<td>Included as standard (for academics only). Users must be academics working for a recognised academic institution.</td>
</tr>
</tbody>
</table>

Once proof of version, academic status and licence key is provided, HIC will install within 3 working days.

HIC is providing this software by agreement with the software provider based upon HIC’s current organisational software licences. However, these agreements are subject to change outside HIC’s control and therefore the benefit of this licence could be revoked and any time.
<table>
<thead>
<tr>
<th>Software vendor</th>
<th>Product</th>
<th>Version</th>
<th>License arrangements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>STATA</td>
<td>STATA MP14 64 bit 3-Aug-2015</td>
<td>Included as standard (for academics only). Users must be academics working for a recognised academic institution. Commercial projects, even when resourced by academic staff, are NOT covered by HIC's academic licencing agreements. Users would need to buy their own commercial licence. HIC are providing this software by agreement with the software provider based upon HIC's current organisational software licences. However, these agreements are subject to change outside of HIC's control and therefore the benefit of this licence could be revoked and any time.</td>
</tr>
</tbody>
</table>

STATA Plugins must be requested individually for installation. Commercial projects, even when resourced by academic staff, are NOT covered by HIC's academic licencing agreements. Users would need to buy their own commercial licence. HIC are providing this software by agreement with the software provider based upon HIC's current organisational software licences. However, these agreements are subject to change outside of HIC's control and therefore the benefit of this licence could be revoked and any time.
<table>
<thead>
<tr>
<th>Software vendor</th>
<th>Product</th>
<th>Version</th>
<th>License arrangements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>any time.</td>
</tr>
<tr>
<td>Notepad-plus-plus.org</td>
<td>Notepad ++ (Open Source)</td>
<td>Build Time</td>
<td>Included as standard</td>
</tr>
<tr>
<td></td>
<td></td>
<td>01/10/15</td>
<td></td>
</tr>
<tr>
<td>Apache OpenOffice</td>
<td>OpenOffice</td>
<td>4.1.1</td>
<td>Included as standard</td>
</tr>
<tr>
<td>Microsoft</td>
<td>Windows</td>
<td>7</td>
<td>Included as standard</td>
</tr>
<tr>
<td>Microsoft</td>
<td>MSOfficePro</td>
<td>2013</td>
<td>Included as standard</td>
</tr>
<tr>
<td>University of Bristol</td>
<td>MLWin</td>
<td>2.35</td>
<td>Included as if requested (for academics only)</td>
</tr>
<tr>
<td>Variable</td>
<td>Specific application software, not on this list</td>
<td>Variable</td>
<td>Subject to HIC approval, HIC will require 5 working days to install on receipt of the software and license key. A fee of £250 is payable for this. All software must be Windows based. HIC are unable to support UNIX or Linux versions of applications.</td>
</tr>
</tbody>
</table>

**Stage 8 - Review of analysis outputs against Statistical Disclosure Controls**

45 When the researcher has completed their analysis, outputs intended for the public domain, for example a table of results, will be reviewed by the GMC using the following statistical disclosure controls*:

45.1 0, 1, 2 are rounded to 0

45.2 All other numbers are rounded to the nearest multiple of 5

45.3 Percentages based on fewer than 22.5 individuals are suppressed

* [https://www.hesa.ac.uk/content/view/146](https://www.hesa.ac.uk/content/view/146)
45.4 Averages based on 7 or fewer individuals are suppressed

45.5 The above requirements relate to headcounts, Full-Person Equivalent (FPE) and Full-Time Equivalent (FTE) data. Financial data is not rounded.

46 Data output requests are processed once per day, between the hours of 9:30 and 11:30 on work-days (except during the 2 week Christmas/New Year period when there will be no Safe Haven support available). All requests made in the previous 24hrs will be processed during this period and shared with the GMC. GMC will review the files in line with statistical disclosure controls and if approved, share the output analysis files with researchers via GMC Connect within 2 working days. Researchers are strongly encouraged to leave sufficient time in their plans for their output to be reviewed before being passed to them.

**Stage 9 - UKMED review of research reports**

47 Research output from UKMED will be reviewed by the Subgroup and reported on to the Advisory Board. This review will assess:

47.1 whether the analysis accords with that originally proposed.

47.2 whether the work includes additional analysis beyond the scope of those agreed within the contract.

47.3 whether the research has met the aims outlined in the proposal.

47.4 whether there are any implications for medical education and/or patient safety.

48 In reviewing the research proposals that are not to be published in peer-reviewed journals, for recommendation to the UKMED Advisory Board, the Subgroup may have regard to the following questions:

48.1 Have the data sources been correctly documented and acknowledged?

48.2 Is the overall design appropriate and adequate to answer the research question?

48.3 Are the data subjects adequately described?

48.4 Have inclusion and exclusion criteria been described?

48.5 Have data quality issues such as data linkage adequacy and missing data been reported?

48.6 Is the sample reported representative of any population it seeks to make inference about?
48.7 Are the methods adequately described?
48.8 Is the derivation of the variables used appropriate and adequately described?
48.9 Are all required statistics reported?
48.10 Is the interpretation warranted by and sufficiently derived from/focused on the data?
48.11 Is the interpretation discussed in the light of previous evidence?
48.12 Are the study limitations noted?

49 The reviewers will identify any specific issues that the UKMED Advisory Board or any of the data providers may wish to consider. For instance concerning reputation, timing of release or prior notice of sensitive findings for relevant parties.

50 When research output includes analysis of data pertaining to one or more college exams, each college involved will be invited to review the output using the subgroup’s criteria. Colleges may nominate any persons they feel best qualified to comment on their behalf. Colleges are not obliged to comment.

51 Colleges may choose to have a representative attend in person or via telephone conference the relevant section of the Research Subgroup’s meeting to discuss the output. This is not obligatory.

52 The review will be completed within four weeks of submission: the outcome would either be a recommendation to the UKMED Advisory Board to publish or request for further work before re-submission.

53 For any of the review questions the Research Subgroup may recommend further work prior to submission to a journal or publication by other means.

54 The output of the subgroup’s peer review typically will only be shared with the submitting researchers and the UKMED Advisory Board. However, applicants should note that the GMC is subject to the Freedom of Information Act and is unable to offer a blanket restriction on disclosure.

55 When the research output is finalised, and no later than one year after the agreed end of research project, an abstract of peer-reviewed publications will be published on the UKMED website, with a reference added upon publication.

56 In case of a research output not intended for peer-review publication, upon being finalised and no later than one year after the agreed end of research project, a full output will be published on the UKMED website.
Appendix A – Illustrative Application Form for access to UKMED data. NOT FOR SUBMISSION

Introduction

57 The GMC is registered as a Data Controller with the UK Information Commissioner’s Office for the purposes of the Data Protection Act 1998 and is the Data Controller for phase 1 of UKMED. The GMC is committed to ensuring that the personal data of doctors and medical students are handled in accordance with the Act.

| Title: | Admin Use Only
Scoring guide (0 - Unacceptable; 1 - Uncertain – may be acceptable with further clarification; 2 - Acceptable) |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary (Please outline your proposed research covering all aspects in max. 250 words):</td>
<td></td>
</tr>
<tr>
<td>References (Please reference up to 5 key papers from your literature review with a sentence explaining the relevance of the paper to the proposed study):</td>
<td></td>
</tr>
<tr>
<td>Research Questions:</td>
<td>Data Required from UKMED (Please specify data items and any filters that should be applied, for example date range):</td>
</tr>
<tr>
<td>---------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>0 - Aims or question not clear. Question appears irrelevant to policy or practice</td>
<td>0 - The data requested is not contained in the UKMED</td>
</tr>
<tr>
<td>1 - Question is poorly defined or uncertain as to whether it is likely to impact on policy or practice if answered. More information or clarification may be required</td>
<td>1 - The data requested is within the database but does not appear capable of answering the research question identified</td>
</tr>
<tr>
<td>2 - Question if answered has significant implications for policy or practice in medical education</td>
<td>2 - The data requested is contained within the UKMED and is well linked to the research question</td>
</tr>
<tr>
<td>Methodology:</td>
<td>0 - Methods not appropriate to addressing research aims or question 1 - Methods may seem outdated, overly simplistic or not well adapted to nature of data 2 - Methodology takes into account the nature of and type of data available and is suitable to address the research question</td>
</tr>
<tr>
<td>Analysis proposed:</td>
<td>0 - Analysis not appropriate to addressing research aims or question 1 – Analysis may seem outdated, overly simplistic or not well adapted to nature of data 2 - Analysis takes into account the nature of and type of data available and is suitable to address the research question</td>
</tr>
<tr>
<td>Proposed Start Date:</td>
<td>Duration:</td>
</tr>
<tr>
<td>Timeline (Key milestones):</td>
<td></td>
</tr>
</tbody>
</table>
Proposal for dissemination of research (E.g. proposed conference submission, proposed journal):

<table>
<thead>
<tr>
<th>0 - No statement of intended use</th>
<th>1 - Intended uses unclear</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 - There is a clear statement on the intended outputs which may include publication in a peer-reviewed journal, publication on an organisation’s website, reports that are evaluations of a service rather than research, or publication as a Ph.D. thesis</td>
</tr>
</tbody>
</table>

Please provide details of all researchers who will be involved in the study and outline each researcher’s proposed role in the study and the working time that will be committed to the research project (e.g. 0.5 FTE):

<table>
<thead>
<tr>
<th>0 - Team is not plausible with little evidence of relevant skills or track record. There is no governance structure defined or there is indication that it may not be accountable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - Team may have obvious skills gaps or limited relevant research track</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lead Researcher’s Title and Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Organisation:</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>Email address:</td>
<td></td>
</tr>
<tr>
<td>Tel/fax:</td>
<td></td>
</tr>
</tbody>
</table>

Brief CVs of the Lead Researcher and other researchers with a significant role:
<table>
<thead>
<tr>
<th>Partners – all those who will have access to the data (Please list name, role, organisation, address, email, tel/fax):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Governance structure is outlined, but is not very clear. Proposed team members have a good track record in related research and are likely to have the skills to employ the proposed methodology and manage data issues. Governance structure is described in a clear and accountable way.</td>
<td></td>
</tr>
</tbody>
</table>

| Is the research funded/does your organisation support the work (Please outline status of any funding application and whether it is essential for the work to proceed. Provide evidence of organisation’s support for work e.g. meeting minutes): | 0 - No explicit plan for how staff time or other resources will be made available to complete the analysis in a timely manner  
1 - Plan for obtaining funding outlined but not guaranteed. Internal institutional support for staff time may be available  
2 - A source of funding has been identified and obtained. This is likely to be sufficient to cover the costs of the work |
Successful applicants will access data via a safe haven, in order to manage this process, please detail the software you will need to use to complete your research.

Please include details of the version number and the terms of your license.

Depending on the software required you may need to bring your own license.

Note that some of the licenses held by some UK universities will permit you to use the given software in the safe haven upon provision of a valid license key provided by your institution. For example, in order to use SPSS free of charge, you will need to provide a valid academic SPSS licence key.
Appendix B – GMC template Data Sharing Agreement

Note highlighted sections to be completed for final contract

Dated [date of contract]

The General Medical Council and [Researcher Organisation(s)]

Agreement relating to the provision of UKMED data for research purposes

Contents

DATED [DATE OF CONTRACT]
THE GENERAL MEDICAL COUNCIL AND [RESEARCHER ORGANISATION(S)]
1. DEFINITIONS AND INTERPRETATION
2. USE OF HEALTH INFORMATICS CENTRE (HIC) DATA SAFE HAVEN
3. HESA STANDARD Rounding METHODOLOGY AND ACKNOWLEDGMENT FOR USE OF DATA
4. ETHICAL APPROVAL, LICENCES AND CONSENTS
5. RESEARCHER AND INSTITUTION STATUS
6. KEY PERSONNEL
7. INTELLECTUAL PROPERTY
8. CONFIDENTIALITY
9. FREEDOM OF INFORMATION
10. DATA PROTECTION
11. WARRANTY, INDEMNITY AND INSURANCE
12. DISPUTE RESOLUTION
13. POLICIES AND STANDARDS
14. ASSIGNMENT AND SUB-CONTRACTING
15. PUBLICITY, MEDIA AND OFFICIAL ENQUIRIES
16. AUDIT
17. NOTICES
18. ENTIRE AGREEMENT
19. GOVERNING LAW AND JURISDICTION

BACKGROUND

1. DEFINITIONS AND INTERPRETATION
2. OBLIGATIONS OF THE GMC
3. OBLIGATIONS OF THE RESEARCHER

This Agreement is made on [Add date]

between (the Parties):
Background

A. The Researcher has submitted a proposal to the UKMED Development Group for access to data which has been approved by the GMC for the purpose of answering the specified research questions.

B. The Researcher requires the provision of certain data in order to support the research. The GMC has agreed to supply the data on the terms and conditions set out in this Agreement.

It is hereby agreed as follows:

1. Definitions and interpretation

1.1 In this Agreement (unless the context otherwise requires), the following words and phrases shall have the following meanings:

**Agreement**: these terms and conditions and each of the attached schedules as varied or amended from time pursuant to the Change Control Procedure;

**Approved Research**: the research referred to in recitals A and B above, set out in the proposal referred to in recital A, which has been approved by the GMC and for which the GMC is agreeing to provide the Data.

**Background Intellectual Property**: the Intellectual Property in works:
(i) existing before the Approved Research started; or
(ii) developed, written or prepared other than in order to provide the Approved Research;

**Commencement Date**: [insert];

**Confidential Information**: all information which is disclosed before or after the Commencement Date by one party to the other however conveyed and which would appear to a reasonable person to be confidential or which is marked confidential or is accompanied by a written statement saying that it is confidential or proprietary, which relates to the business, products, developments, trade secrets, know-how, personnel, customers and Researchers of the party disclosing it, and all information derived from the above;

**The Data**: the Data placed in the Safehaven by the GMC as described in clause 2.1.

**Derived data**: all data-fields generated by you whilst undertaking your research project using the UKMED data. This, in effect, is your final working dataset, including the
analytical dataset used together with all newly-generated data-fields. This includes derived data-fields created from analysis of existing data, plus all intermediates of those derived data-fields.

**Dispute Resolution Procedure:** the procedure set out at clause 13;

**DPA:** the Data Protection Act 1998;

**Employee:** any person employed or engaged by the Researcher or any of its agents, subcontractors, Researchers or associates;

**Ethical Approval:** any approvals or consents to be obtained from professional or other bodies that are required by the Researcher for the performance of the Approved Research or any of them;

**FOI Legislation:** Any or all of the Environmental Information Regulations 2004, the Environmental Information (Scotland) Regulations 2004, the Freedom of Information Act 2000 or the Freedom of Information (Scotland) Act 2002, or any subsequent legislation which amends or replaces them;

**Foreground Intellectual Property:** the intellectual property in works developed, written or prepared by the Researcher (or its subcontractors or consultants);

**HESA Standard Rounding Methodology:** is the application of the following processes to data or statistics:

- 0, 1, 2 are rounded to 0.
- All other numbers are rounded to the nearest multiple of 5.
- Percentages based on fewer than 22.5 individuals are suppressed.
- Averages based on 7 or fewer individuals are suppressed.
- The above requirements relate to headcounts, FPE and FTE data.

Or such other rounding methodology as HESA may from time to time notify to the GMC as replacing the methodology described here.

**Intellectual Property:** means patents, inventions, know how, trade secrets and other confidential information, registered designs, copyrights, database rights, design rights, rights affording equivalent protection to copyright, database rights and design rights, semiconductor topography rights, trade marks, service marks, logos, domain names, business names, trade names, moral rights, and all registrations or applications to register any of the aforesaid items, rights in the nature of any of the aforesaid items in any country or jurisdiction, rights in the nature of unfair competition rights and rights to sue for passing off;

**Key Personnel:** the persons specified in clause 6 of this Agreement, or otherwise notified by the Researcher to the GMC and approved by the GMC as provided for in clause 6;
**Request for Information:** a request for information to which this Agreement applies which falls within the FOI Legislation, or a request which appears to fall within that description;

**Researcher Personnel:** any employees, workers, agents, consultants and officers of the Researcher (or any subcontractor engaged by the Researcher) and any individuals contracted to the Researcher (or to any such Researcher subcontractor) who are involved in the performance of the Approved Research;

**Staff:** all persons employed by the Researcher to perform its obligations under this Agreement together with the Researcher’s servants, agents, Researchers and subcontractors used in the performance of its obligations under this Agreement;

**Syntax:** the script/code used to generate your results in the software employed.

**Working Day:** any day from Monday to Friday (inclusive) which is not a Bank Holiday in England and Wales.

1.2 In this Agreement (unless the context otherwise requires):

1.2.1 The words including and include and words of similar effect shall not be deemed to limit the general effect of the words which precede them;

1.2.2 Reference to any agreement, contract, document or deed shall be construed as a reference to it as varied, supplemented or novated;

1.2.3 Obligations undertaken by a party which comprises more than one person shall be deemed to be made by them jointly and severally;

1.2.4 Words importing persons shall include firms, companies and bodies corporate and vice versa;

1.2.5 Words importing the singular shall include the plural and vice versa;

1.2.6 Words importing any one gender shall include either other gender;

1.2.7 References to a numbered clause, schedule or paragraph are references to the clause, schedule or paragraph of this Agreement so numbered;

1.2.8 Reference to any legislative provision shall be deemed to include any statutory instrument, by-law, regulation, rule, subordinate or delegated legislation or order and any rules and regulations which are made under it, and any subsequent re-enactment or amendment of the same; and

2. **Use of Health Informatics Centre (HIC) Data Safe Haven**

2.1 The GMC shall place pseudonymised data within the HIC Safehaven, University of Dundee HIC Services, Second Floor, Level 7, Mail Box 15, Ninewells Hospital & Medical School, Dundee, DD1 9SY (“the Safehaven”), where the Recipient can access a
pseudonymised dataset to undertake the Approved Research. Such access shall be available for a specified period notified to the Recipient following signature of this Agreement.

2.2 The Recipient in accessing the Data from the Safehaven shall:

2.2.1 only process the Data:

2.2.1.1 to undertake the Approved Research; and

2.2.1.2 to the extent and in such a manner as necessary for the Approved Research;

2.2.2 not extract, copy, print, or in any way remove the Data from the Safehaven without the prior approval of the GMC;

2.2.3 only extract Data subject to the HESA Standard Rounding Methodology specified in clause 3 and approved and authorised by GMC to be extracted by the Recipient from the Safehaven as an Output under clause 2.2.6;

2.2.4 implement appropriate technical and organisational measures to protect the Data against unauthorised or unlawful processing and against accidental loss, destruction, damage, alteration or disclosure. Such measures shall be appropriate to the nature of the Data and the Purpose; and

2.2.5 notify the GMC of any accidental or deliberate unauthorised loss, destruction, damage, alteration or disclosure of the Data and take all reasonable steps to recover or ensure secure deletion of the Data; and

2.2.6 not to use the Data, or allow others to use the Data, to identify or attempt to identify individuals or to make decisions or enable any decisions to be made about an individual, or to contact or attempt to contact any individual.

2.2.7 not allow the Data to be accessed by any Researcher Personnel other than the Key Personnel.

2.3 When the Recipient has finalised their analysis of the Data, the analysis ("the Output") will be sent using a secure file transfer to the GMC by HIC to be checked for any risk that individuals are identifiable or potentially identifiable from the Output and to ensure that the HESA Standard Rounding Methodology has been applied in preparation of the Output as required by clause 2.2.3. Where no such risk is identified and the Rounding Methodology has been applied, the Output will be released to the Recipient by the GMC via a secure file transfer.

2.4 Where the Output has not been approved for release under clause 2.3, the reason for this will be explained to the Recipient who will be asked to amend the Output, including through application of the HESA Standard Rounding Methodology, to remove any risk of identifiability.
2.5 The Data will be retained by its Safe Haven provider for a period of seven years from the commencement date. On completion of the Approved Research, the Recipient may apply to the GMC to re-access the Data where this is necessary to check the accuracy of their original analysis.

3. **HESA standard Rounding Methodology and acknowledgment for use of data**

3.1 The Data includes information derived from data collected by the Higher Education Statistics Agency Limited ("HESA") and provided to the GMC ("HESA Data"). HESA makes no warranty as to the accuracy of the HESA Data and does not accept responsibility for any inferences or conclusions derived from its data by third parties.

3.2 Where the Recipient uses, reproduces or references in a publication HESA Data the Recipient shall:

3.2.1 acknowledge HESA as a source of the data and make clear that HESA does not accept responsibility for any inferences or conclusions derived from HESA Data by third parties e.g.

- Source:
- HESA Student Record 20XX/YYs
- Copyright Higher Education Statistics Agency Limited

The Higher Education Statistics Agency Limited cannot accept responsibility for any inferences or conclusions derived by third parties from data or other information supplied by it; and

3.2.3 ensure that the HESA Rounding Methodology as defined in paragraph 3.3 has been applied.

3.3 The "HESA Standard Rounding Methodology" is the application of the following processes to data or statistics:

- 0, 1, 2 are rounded to 0.
- All other numbers are rounded to the nearest multiple of 5.
- Percentages based on fewer than 22.5 individuals are suppressed.
- Averages based on 7 or fewer individuals are suppressed.
- The above requirements relate to headcounts, FPE and FTE data.
Or such other rounding methodology as HESA may from time to time notify to the GMC as replacing the methodology described here.

4. **Ethical Approval, licences and consents**

4.1 The Researcher will obtain all relevant Ethical Approvals. On written request from the GMC, the Researcher will immediately provide copies of Ethical Approvals obtained in relation to their project or evidence that Ethical Approval is not required for their project.

4.2 If any licence or consent of any government or other authority is required, the Researcher will obtain and maintain such licence or consent at its own expense and produce evidence of it to GMC immediately upon GMC’s written request.

5. **Researcher and Institution status**

5.1 The Researcher confirms that this research project is not commercially funded and does not form part of a commercially funded project.

6. **Key Personnel**

6.1 The following persons will require access to the Safehaven. Subject to clause 6.2, such persons shall be Key Personnel for the purposes of this Agreement:

<table>
<thead>
<tr>
<th>Name</th>
<th>Role/Responsibility</th>
<th>Email contact address</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Insert]</td>
<td>[Insert]</td>
<td>[Insert]</td>
</tr>
</tbody>
</table>

6.2 The Researcher may appoint additional or replacement Key Personnel to those individuals specified in clause 6.1, provided that such appointments shall be subject to the prior written approval of the GMC (such approval not to be unreasonably withheld or delayed).

6.3 The Researcher shall ensure that all Key Personnel are subject to explicit contractual obligations to comply with the conditions on access to the Data which are set out in this Agreement and generally to keep the Data confidential and secure.

7. **Intellectual Property**

**Background IPR**
7.1 GMC's Background Intellectual Property will remain vested in GMC.

7.2 Background Intellectual Property of HESA or any other third party shall remain vested in HESA or another third party (as the case may be).

7.3 The Researcher's Background Intellectual Property will remain vested in the Researcher (or third party proprietor as the case may be).

7.4 Where, as part of its Background Intellectual Property, GMC provides third party Intellectual Property to the Researcher, it shall use reasonable endeavours to ensure that the Researcher is authorised to use such third party Intellectual Property for the purposes of the research project to which this Agreement relates.

7.5 All Foreground Intellectual Property will vest in the Researcher.

7.6 All rights in the name and logo of each party shall remain the absolute property of that party and the other party shall not by virtue of this Agreement acquire any rights or interest therein. Neither party shall use or exploit the other party's name or logo in any way without the prior written consent of the other party.

8. **Review by UKMED Development Group prior to publication**

8.1 The GMC acknowledges that the Researcher has a responsibility to make academic publications to demonstrate carrying out of its primary purposes; that is the advancement of education through research. The GMC is content to support this subject to the conditions below:

   8.1.1 The Researcher will provide a copy of all proposed publications, derived data and syntax to the GMC for presentation to the UKMED Development Group not less than thirty (30) days in advance of the submission for publication.
   8.1.2 The GMC retains the right to veto (and in doing so, withdraw consent for the Researcher to use any material to which the GMC owns the intellectual property rights in academic publications) any proposed publication that is factually inaccurate with regard to the role, structure and function of the GMC or other contributing organisation.
   8.1.3 The GMC shall notify the Researcher of any veto within thirty (30) days after the receipt of the material, failing which the Researcher shall be free to assume that there is no issue and they are free to publish.

8.2 Where the Researcher wishes to use the information for any other purpose that is not related to the original purposes of the research, it shall request the GMC's specific prior written approval.

**General**
8.3 Where either party becomes aware of any infringement or allegation of infringement of Intellectual Property, that party shall:

8.3.1 Promptly notify the other party in writing of such infringement or allegation of infringement;

8.3.2 Where the other party is the owner of the infringing or allegedly infringing Intellectual Property:
   (a) Allow the other party to conduct all negotiations and proceedings and give the other party all reasonable assistance; and
   (b) Make no admission relating to the infringement or alleged infringement.

8.4 Notwithstanding any other provision of this Agreement, the licences granted under clause 7 will survive any termination of this Agreement.

9. Confidentiality

9.1 All Confidential Information given by one party to the other, or otherwise obtained or developed by one party relating to the other, shall be kept secret and confidential by the receiving or developing party (as applicable) throughout the term of this Agreement and following its termination or expiry for any reason and the receiving or developing party shall not use such Confidential Information other than for the purposes of the proper performance of this Agreement without the prior written consent of the other party.

9.2 The obligations of confidentiality in this clause shall not extend to any information which the receiving party can show:

9.2.1.1 Was independently disclosed to it by a third party entitled to disclose the same; or

9.2.1.2 Is required to be disclosed under any applicable law, or by order of a court or governmental body or authority of competent jurisdiction.

9.3 The obligations contained in this clause shall not apply to:

9.3.1.1 The use or publication of any material in accordance with clause 10 of this Agreement; or

9.3.1.2 Any disclosure made pursuant to the FOI Legislation.

9.4 If confidential data is provided to the Researcher in an anonymised/pseudonymised form, the Researcher should not, and should not support or allow third parties to:
9.4.1.1 Attempt to deduce the identity of individuals by a process of triangulation, which involves using other datasets to bypass anonymisation/pseudonymisation to identify individuals.

9.4.1.2 Use information, accidentally or otherwise, gleaned from identifying individuals by triangulation to make any decisions in relation to an individual.
10. **Freedom of information**

10.1 The Researcher acknowledges that GMC is subject to the requirements of the Freedom of Information Act 2000 (FOIA) and shall assist and cooperate with GMC to enable GMC to comply with its information disclosure obligations.

10.2 The Researcher shall and shall procure that its sub-contractors shall:

10.3 Transfer to GMC all Requests for Information that it receives as soon as practicable and in any event within two (2) Working Days of receiving a Request for Information;

10.4 Provide GMC with a copy of all information in its possession or power in the form that GMC requires within five (5) Working Days of GMC's request; and

10.5 Provide all necessary assistance as reasonably requested by GMC to enable GMC to respond to the Request for Information within the time for compliance set out in section 10 of FOIA or regulation 5 of the Environmental Information Regulations 2004.

10.6 GMC shall be responsible for determining in its absolute discretion and notwithstanding any other provision in this Agreement or any other agreement whether any information is to be disclosed or published, or is exempt from disclosure in accordance with the provisions of the FOIA.

10.7 In no event shall the Researcher respond directly to a Request for Information unless expressly authorised to do so by GMC.

10.8 The parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA, the content of this Agreement is not confidential.

Or

10.9 Each party acknowledges that the other party is subject to the requirements of the FOI Legislation and shall assist and cooperate with the other party to enable the other party to comply with its information disclosure obligations.

10.10 Where either party receives a Request for Information which relates to information held pursuant to this Agreement, the other party shall respond within five (5) Working Days to any request by the receiving party for:

10.11 Assistance in determining how to respond to a Request for Information; and/or

10.12 The provision of information held by the other party pursuant to this Agreement.

10.13 Where either party receives a Request for Information which relates to information held pursuant to this Agreement, prior to responding to such request, that
party will consult with the other party in relation its response and will allow the other party to make representations with respect to:

10.14 Any information which the other party regards to be confidential; and/or

10.15 Any similar or identical request received by the other party and (where applicable) the other party’s response to that request.

10.16 Notwithstanding the provisions of clauses 10.9 to 10.13 (inclusive) each party acknowledges that the decision on whether any exemption applies to a request for disclosure of recorded information is a decision solely for the party receiving a Request for Information.

10.17 The parties acknowledge that, except for any information which is exempt from disclosure in accordance with the provisions of the FOI Legislation, the content of this Agreement is not confidential.

11. Data protection

11.1 The parties shall comply with the Data Protection obligations which are set out in Schedule 2 to this Agreement.

11.2 Notwithstanding the general obligation in clause 11.1, the Researcher shall:

11.2.1 Provide the GMC with such information as the GMC may reasonably request to satisfy itself that the Researcher is complying with its obligations under the DPA;

11.2.2 Promptly notify the GMC of any breach of the security measures to be put in place pursuant to this clause; and

11.2.3 Ensure that it does not knowingly or negligently do or omit to do anything which places itself or the GMC in breach of obligations under the DPA.

12. Warranty, indemnity and insurance

12.1 The Researcher warrants, represents and undertakes that:

12.1.1 It has full capacity and authority to enter into and to perform this Agreement and that this Agreement is executed by a duly authorised representative of the Researcher;

12.1.2 It will obtain full Ethical Approval prior to the date at which such Ethical Approval is required in order to commence or continue to provide the Approved Research or any part thereof;
12.1.3 It has obtained and will maintain all necessary rights, consents, authorisations to perform its obligations in accordance with this Agreement;

12.1.4 It will undertake the Research with all the skill, care, diligence and foresight that would be expected from a Researcher, to a high standard including (without limiting the generality of this clause) in accordance with the Researcher’s own established internal procedures;

12.1.5 All personnel assigned will have the requisite training, experience, qualifications and knowledge necessary to carry out the tasks assigned to them and in so doing will adopt reasonable and proper standards of behaviour.

12.1.6 The Researcher will, for the entire duration of the Agreement (including any extension period) and for one year following the end of the Agreement (including any extension period), insure and keep itself insured with a reputable insurance company against all insurable liabilities under this Agreement and in respect of the Approved Research including, without limitation against all the Researcher’s liabilities under this clause 10.

13. Dispute resolution

If any dispute arises out of this Agreement the dispute shall be referred to the [insert Researcher Senior Representative] and the Assistant Director, Research of GMC who will attempt to settle it by negotiation. If the parties are unable to settle any dispute by negotiation within ten (10) Working Days the parties may elect to refer the dispute to mediation or an alternative form of dispute resolution. However, nothing in this clause shall prevent the parties commencing or continuing court proceedings at any time.

14. Policies and Standards

14.1 When performing the Approved Research, the Researcher shall comply with the policies and standards set out in Schedule 3 ("the Policies and Standards") as amended from time to time in the event that there is a conflict between the Policies and Standards and this Agreement the terms of this Agreement shall take precedence.

15. Assignment and sub-contracting

15.1 The Researcher shall not assign, transfer or otherwise deal with any of its rights or obligations under this Agreement, or sub-contract the performance of any of its obligations under this Agreement without the prior written consent of GMC.

15.2 Any sub-contract entered into by the Researcher shall be on no less onerous terms than those set out in this Agreement, provided that no sub-contracting by the
16. **Publicity, media and official enquiries**

16.1 Without prejudice to the GMC’s obligations under the Freedom of Information Act 2000, the Researcher shall not make any press announcement or publicise this Agreement or any part thereof in any way, except with the prior written consent of the GMC and other contributing organisation, as appropriate.

16.2 The Researcher shall take reasonable steps to ensure that their servants, employees, agents, sub-contractors, Researchers, professional advisors and consultants comply with clause 12.1.

17. **Audit**

17.1 The Researcher shall keep and maintain until six years after the end of the Agreement, or as long a period as may be agreed between the Parties, full and accurate records of the Agreement.

18. **Notices**

18.1 Any notice given by one party to the other under this Agreement must be in writing and may be delivered via email, personally or by pre-paid first class post and in the case of post will be deemed to have been given two Working Days after the date of posting. Notices shall be delivered or sent to the addresses of the parties on the first page of this Agreement or to any other address notified in writing by one party to the other for the purpose of receiving notices after the date of this Agreement. Each party may specify by notice to the other a particular individual or office holder to whom any notices served on it are to be addressed, in which case a notice shall not be validly given unless so addressed.

19. **Entire agreement**

19.1 This Agreement sets out the entire agreement and understanding between the parties in respect of its subject matter and supersedes all former warranties, statements, representations, understanding, undertakings and agreements (in each case whether written or oral) made by or between the parties relating to such subject matter and including without limitation the terms set out in any document produced by the Researcher, notwithstanding the terms of any previous agreement or arrangement expressed to survive termination.
20. **Governing law and jurisdiction**

20.1 This Agreement and any matter arising from or in connection with it shall be governed by and construed in accordance with English law.

20.2 Each party irrevocably agrees to submit to the non-exclusive jurisdiction of the English courts over any claim or matter arising from or in connection with this Agreement. In witness whereof the parties have executed this Agreement the day and year first above written.

**Schedule 1**

**Part A – Data Specification**

**Schedule 2**

**Data Protection**

**Background**

In order to perform the Approved Research on GMC's behalf, the Researcher may require access to certain Data (as defined below) to be made available to it by GMC. The main part of this Agreement sets out the basis on which such access will be provided the arrangements for such access and some of the conditions on the grant of such access. The provisions below further regulate the provision and use of the Data, with the aim of ensuring that access to and use of Data under this Agreement complies fully with the Data Protection Act 1998.

**1 Definitions and interpretation**

1.1 In this Schedule 2 (unless the context otherwise requires), the following words and phrases shall have the following meanings:

**Act:** the Data Protection Act 1998.
**Data Controller:** the individual or organisation who determines the purposes for which and the manner in which any personal data are, or are to be, processed.

**Data Processor:** a third party who processes personal data on behalf of the Data Controller.

**Personal Data:** any and all personal data (as such term is defined in the Act) provided or made available (whether directly or indirectly, including the Data provided through the Safehaven, and in whatever form) by the GMC to the Researcher pursuant to this Agreement. This will include data provided in an pseudonymous format and any further information relating to individuals which one might reasonably expect to regard as confidential.

**Data Subject:** means an individual who is the subject of personal data.

**European Economic Area:** The EEA countries are currently the EU countries plus Iceland, Liechtenstein and Norway and for the purposes of this Agreement will include any country on the EU Commission’s list of countries or territories providing adequate protection for the rights and freedoms of data subjects in connection with the processing of their personal data.

2 **Obligations of the GMC**

The GMC shall provide access to Personal Data to the Researcher through the Safe haven together with such other information as the Researcher may reasonably require in order for the Researcher to perform the Research.

3 **Obligations of the Researcher**

3.1 The Researcher will be a Data Controller and they are entirely responsible for full compliance with their obligations under the DPA.

3.2 The Researcher shall:

3.2.1 Implement appropriate technical and organisational measures to protect Personal Data against unauthorised or unlawful processing and against accidental loss, destruction, damage, alteration or disclosure. Such measures shall be appropriate to the harm that might result from unauthorised or unlawful processing or accidental loss, destruction or damage to Personal Data and to the nature of Personal Data to be protected;

3.2.2 comply with all applicable laws, regulations, regulatory requirements and codes of practice, in connection with its obligations under this Agreement, including without limitation by complying with all the provisions of the DPA and not do anything which may result in a breach by the GMC of the same; and
3.2.3 promptly notify the GMC if it receives a request from a Data Subject to have access to Personal Data within the data accessed under this Agreement or any complaint or request relating to the GMC's obligations under the DPA and provide full cooperation and assistance to the GMC in relation to any such complaint or request (including, without limitation, by allowing Data Subjects to have access to their Personal Data if agreed by the GMC).

3.3 The Researcher shall not process Personal Data outside the European Economic Area or transfer Personal Data outside the European Economic Area without the advance agreement of the GMC’s Information Policy Section that it will be adequately protected.

3.4 At the reasonable request and expense of the GMC, the Researcher shall assist the GMC in complying with its obligations in its activities as a Data Controller.

3.5 In this Schedule 2 (unless the context otherwise requires) an obligation in this Agreement on the Researcher to do, or refrain from doing, any act or thing shall include an obligation to procure that its employees, agents and sub-contractors (if any permitted) also do, or refrain from doing, such act or thing. This includes ensuring that any subcontractor or agent shall comply with obligations equivalent to those of the Researcher.

Schedule 3

Policies and Standards

Data Protection and Information Security from the researcher’s host organisation.
Execution

Signed by [removed] for and on behalf of [removed]
General Medical Council [removed]

Signed by [removed] for and on behalf of [removed]
[the Researcher] [removed]
Appendix C - Data User Agreement to access the HIC Safe Haven for approved UKMED Research Projects

Data User Responsibilities

The Approved Data User is reminded of the sensitive nature of the data being accessed and is required to maintain the security and confidentiality of the Project Dataset in accordance with this HIC Data User Agreement and the Data Protection Principles (attached in Appendix A forming a part of this Agreement). HIC requires Approved Data Users to report inadvertent events that are in breach of the terms of the HIC Data User Agreement to enable improvements to be made. Contact the HIC Governance Manager in the first instance to report the incident, who will initiate a Significant Event Report and report any outcome to the GMC.

The Approved Data User:

1.1) Will complete suitable information governance training, e.g. the MRC e-learning module Research Data and Confidentiality.

1.2) Will not reuse the Project Dataset for purposes outside the scope of the Project; attempt to link it to other datasets; or to de-anonymise it.

1.3) Agrees to ensure that individual-level data is not transferred outside the safe haven via any means including, for example (not exhaustive); photographic, recording, screen grabbing and note taking. If you are in doubt please contact HIC for further advice and assistance.

1.4) Must never share or disclose their Safe Haven login details.

1.5) Must never allow people who do not have approved access to a Project to see individual level data from that Project within the Safe Haven.
1.6) Must make every effort to stop people who do not have personal access to a Project viewing data about that Project on the Safe Haven screen (e.g. refraining from using via a laptop in public spaces).

When the Project is complete the data and analysis syntax used will be archived by HIC.

Approved Data Users may utilise existing University of Dundee agreements for the use of a set of standard statistical software packages within the safe haven for non-commercial academic studies, where the Approved Data User works for an academic institution. Due to the different licensing rules of statistical software providers different terms and conditions will apply. Statistical software access for each study and the terms and conditions of each package can be confirmed with the Manager of HIC’s Data Linkage Service.

The Approved Data User is *(tick as appropriate)*:

- [ ] An academic
- [ ] A non-academic

The Approved Data User works for:

- [ ] An academic institution
- [ ] A commercial institution
- [ ] Other (please specify) __________________________

**Glossary**

Project: means a unique study with a PI, specified cohort, aims and methods that are logged into the HIC Project Management System and all required governance approvals have been provided to GMC.

Project Dataset: means the data that has been anonymised uniquely and is specifically for use within a Project. The dataset must relate to the cohort and purpose defined for the Project and is placed in the Safe Haven Project folder to be accessed by an Approved Data User. A signed Data User Agreement will permit an Approved Data User to access Project Datasets, as authorised by a Project PI and recorded on the HIC Project Management System.
Signatures

1a) Declaration by Applicant for Approved Data User Status

By signing and dating below (but not as a party to this HIC Data User Agreement) you hereby declare and confirm that you understand and agree to the terms of this HIC Data User Agreement and the Data Protection Principles which will govern the Project Dataset(s) being provided to the Institution from GMC which you are applying to access.

Name: ______________________________________ ("the Applicant")

Position: ______________________________________

Institution: ______________________________________

Signature ___________________________ Date signed: ______________________

1b) Applicant’s Organisation

Approved Data Users must have this section signed by an authorised signatory from their organisation, the Institution named below.

An authorised signatory for the project collaborator’s Institution is to sign the following declaration:

The Institution named below hereby agrees that the Applicant named in section a) above is a bona fide employee or student of this Institution engaged in a reputable Project for which all relevant required permissions have been granted, and that the Project Dataset requested can be entrusted to this person in the knowledge that they will conscientiously discharge their obligations in regard to the confidentiality of the Project Dataset. This Institution agrees to abide by the terms of this HIC Data User Agreement and shall take responsibility for ensuring that the proposed Approved Data User complies with the terms of this HIC Data User Agreement, Appendix A and all applicable statutory and regulatory permissions and Data Protection requirements. The Institution agrees to provide a secure working environment and suitable technical resources to meet this obligation.
The Institution agrees that a breach of this HIC Data User Agreement may lead to the withdrawal of access to the HIC Safe Haven for this Institution, its staff and students, and that GMC and HIC have a duty to report serious legal or regulatory breaches to the appropriate authorities (such as the Data Protection Commissioner and professional regulatory bodies).

Name: ______________________________
Position: ______________________________
Signature ___________________________ Date signed: ___________________________

For and On behalf of: ______________________________
                       (Name of Institution)

1c)  GMC Data User Authorisation

GMC authorised signatory confirming the above Applicant is approved to access GMC data within the HIC Data Safe Haven. Specific Project access approval is provided separately, per Project.

Name: ______________________________
Position: ______________________________
Signature ___________________________ Date signed: ___________________________
Appendix A: The 8 Data Protection Principles

1. Personal data shall be processed fairly and lawfully
   - must not deceive or mislead
   - must state the purpose of the processing
   - must provide your identity
   - must have consent of the data subject – cannot infer this from a lack of response
   - must specify time period of consent
   - must have appropriate safeguards for data
   - must obtain consent from data subjects for processing if data provided by a third party

2. Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or purposes
   - Must identify purposes for which data is being processed
   - Must ensure purposes are compatible with information given to data subjects and to the Office of the Information Commissioner (www.ico.gov.uk)
   - Must not further process if purposes are not compatible with consent or notification to OIC without resolving conflicts

3. Personal data shall be adequate, relevant, and not excessive in relation to the purpose or purposes for which they are processed
   - Must establish what is collected and why
   - Must audit data holding against need – minimum information must be collected – do not collect ‘just in case’
   - Must establish effective data retention and disposal policies
Must establish policies and procedures to test new and modified data collection against the principles

4. Personal data shall be accurate and, where necessary, kept up to date
   - Must establish methods to validate the source of data
   - Must establish policies and procedures to keep data up-to-date
   - Must establish policies and procedures to correct or mark as incorrect any disputed data

5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes
   - Must establish policies and procedures review why you are retaining data – e.g. current use, audit/ legal purposes, research purposes
   - Must delete data that is no longer needed

6. Personal data shall be processed in accordance with the rights of data subjects under this Act
   - Rights of data subjects include:
     - Right to be told that their personal data is being processed and for what purpose
     - Right to obtain a copy of their personal data
     - Right to prevent the use of their data for direct marketing purposes
     - Right to be told to whom the data will be disclosed
     - Right to prevent processing which may cause substantial damage or distress to the data subject
     - Right to have explained the logic behind any decision taken on the basis of the processing of the data
Must manage operations to ensure that data subjects can exercise their rights properly and fully.

7. Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.

- Practical steps to compliance include:
  - Do not allow staff to share password.
  - Site PCs where the screen cannot be seen by unauthorised staff or the public and do not leave information on the screen when you are not there.
  - When using external agencies ensure processing is carried out under written contracts.
  - Block access to systems by former staff.
  - Vet all prospective employees.
  - React to allegations of access to unauthorised data.
  - Do not leave files unattended in the open.
  - Shred personal data rather than bin it.
  - Do not design documents/write papers in ways that reveal personal data.
  - Physical and electronic security.
  - Staff training.
  - Measures to prevent accidental loss, damage or destruction of data.

8. Personal data shall not be transferred to a country or territory outside the European Economic Area (25 EU Member States + Iceland, Lichtenstein & Norway) unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

- Must not transfer data by any means (including electronic) if in doubt.
Researchers
-- UKMED
GMC – the Data Controller

Researchers working remotely using the safe haven

**Stage 2** Application for UKMED Research submitted (UKMED application form)

Stage 3 UKMED Research subgroup review application against criteria and report on quality against criteria to development group

- Is clarification required?
  - Yes
    - Development group review commentary and scoring and makes a recommendation to the GMC
  - No

Will the dataset be provided to support the research proposal?

- Yes
  - Stage 4 - GMC finalise data specification

- No
  - Stage 5 - Complete data sharing agreement between researchers and GMC as data controller

Stage 6 - Identifying dataset: study codes and degrade where required to satisfy K-anonymity

Stage 7 – software arrangements and configuring the safe haven

Stage 8 Outputs reviewed against Statistical Disclosure Control rules: HESA’s Standard Rounding Methodology

Further analysis

Stage 9 UKMED Research subgroup review report

Further Work required?

- Yes
  - Development Group to have sight of findings and subgroup report

- No - Work met all criteria
  - Subgroup review report

With existing data

With revised data

Researchers

Stage 8 - Write-up analysis into report(s)

End

Stage 1 - Support for the project confirmed

Stage 1 - Ethical approval or exemption received

Stage 4 - GMC finalise data specification

Stage 5 - Complete data sharing agreement between researchers and GMC as data controller

Stage 6 - Produce data set

Stage 7 - Complete analysis

Stage 8 - Outputs reviewed against Statistical Disclosure Control rules: HESA’s Standard Rounding Methodology

Stage 9 UKMED Research subgroup review report

Further Work required?

- Yes
  - Development Group to have sight of findings and subgroup report

- No - Work met all criteria
  - Subgroup review report

With existing data

With revised data

End

Figure 1 Process for completing UKMED Research