**New Client request for access to CPRD Data**

Clinical Practice Research Datalink (CPRD) is a dedicated UK Government initiative jointly supported by the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health Research (NIHR) to promote healthcare research and drive innovation through use of UK patient electronic health records (EHR). For more than 30 years, CPRD has been providing routinely collected, anonymised EHR data to enable high quality observational health research conducted by academic researchers, regulators and the life science industry worldwide. CPRD is dependent on public support for continued use of its data as a unique and valuable research resource.

To ensure patient confidentiality and public support for CPRD services, CPRD wishes to ensure that its data is used only by bona fide research organisations conducting public health research. Potential clients of CPRD data are therefore requested to provide the following information to CPRD’s Senior Management Team to determine the organisation’s suitability to access CPRD data.

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| **Organisation information:** | |
| Organisation name and registered address  *Please include company number for commercial Organisations* |  |
| Organisation (including affiliates) type and main business activities  *CPRD is unable to licence data to Organisations engaging in activities that may undermine patient and public trust in CPRD’s data stewardship role* |  |
| Is the applying organisation controlled or owned by any entry on the official UK sanctions list [https://www.gov.uk/government/publications/the-uk-sanctions-list](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fthe-uk-sanctions-list&data=05%7C01%7CSherlin.Au%40mhra.gov.uk%7Cc4f51c54b8e9451a884108db31d12315%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638158546519139430%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=vsgjnaHS725a9a6hk%2FAQNp5TwH3sVd0I%2F3ZGGIvX5nY%3D&reserved=0) ? | Yes / No |
| Has the Organisation conducted public health research using large health research databases previously?  *Please provide bibliographic references for 5 recent publications* |  |
| Expected public health benefits of proposed research to be conducted with CPRD data |  |
| Is the Organisation wishing to become a direct client of CPRD?  *If not and the Organisation intends to access CPRD data via a CPRD licensed client, please provide the name of the relevant CPRD licensed client* | Yes / No |
| Who will fund the proposed research?  *CPRD is required to publish a list of its direct clients and funding organisations that may benefit directly from the research* |  |
| Territory of use of data |  |
| **Information to be provided:** | |
| CV for all proposed data users (see appendix 1 for required CV template)  *To demonstrate qualifications of user as a bona fide researcher experienced in the use of large health research datasets for public health research* |  |
| Organisation’s financial reports  *Please provide the Organisation’s last three (3) years audited accounts.* |  |
| Data security standards adhered, certified, or accredited to by the Organisation and any applicable data hosting third party/service.  *If adhering to standards, a clear articulation of how the organisation and data hosting third party/service conforms to these standards must be provided. This should be demonstrated and supported by appropriate documentation.*  *If certified or accredited to standards, this must be clearly demonstrated. This should include, but is not limited to, the following:*  *If ISO27001 certified, a copy of the certificate and Statement of Applicability.*  *If NHS Data Security & Protection Toolkit accredited, the applicable ODS number(s).* |  |
| Has the Organisation had an information security incident or data breach in the last five (5) years?  *Instances of both internally and externally reported incidents and/or data breaches must be considered in your response.*  *If yes, please provide details about the nature of the incident/breach and the measures in place to prevent and manage a similar event in the future.* |  |
| Explain what measures are in place to ensure CPRD data is isolated from other datasets available to the Organisation? |  |
| Organisation’s data protection policy  *Please provide website links or attachments* |  |
| Organisation’s information security policy  *Please provide website links or attachments* |  |
| Organisation’s information classification policy, and what classification CPRD data will be given?  *Please provide website links or attachments* |  |
| What data protection and information security training are provided by the Organisation to staff and users of CPRD data, and how often is it delivered? |  |
| What procedures are in place by the Organisation:   1. to ensure the confidentiality of CPRD data (i.e. only authorised individuals have access to the data for authorised purposes); 2. to ensure the integrity of CPRD data (i.e. manipulation of CPRD data is controlled); 3. to ensure the availability of CPRD data (i.e. data is kept readily available for those who have authorisation to access it); 4. for the identification, classification, treatment, and ongoing monitoring of information risks; 5. for the notification of information security incidents and data breaches, and; 6. for data disposal. |  |
| Proposed dissemination and publication policy arising from use of data  *Data is made available for public health research with the intention that the results of the study will be publicly available* |  |

If the Organisation is approved as a direct client of CPRD, CPRD and the Organisation will enter in to a contractual licence affirming the full terms and conditions of access.

If the Organisation is approved as a third-party client of CPRD, CPRD’s licensed client named above and the Organisation will enter into a contractual licence affirming the full terms and conditions of access

To fulfil CPRD’s obligations to the data custodians, CPRD wishes to make the Organisation aware of the following restrictions on use of the data and other non-negotiable terms in the licence:

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| **Restrictions on use:** |
| Data is non-transferrable (other than as permitted in the licence) and confidential in nature |
| Data is not to be used to identify, contact or target patients or general medical practitioners |
| Data is not to be used to study the effectiveness of advertising campaigns or sales forces |
| Data is not to be merged with other data |
| Data is not to be sold, traded or otherwise disposed of |
| **Non-negotiable licence requirements:** |
| CPRD (and data custodians) to be permitted access to audit Organisation’s use of the data |
| Details of any licensed client will be shared with data custodians and available to the public |

To the best of Organisation’s knowledge, the information provided above is accurate at the time of writing confirmed by authorised signatories:

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Role: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Approved/Not approved by CPRD:

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Role: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **CPRD Comments** |
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**Appendix 1:** CV template

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| **Title** (Dr/Prof etc.) |  |
| **Forename** |  |
| **Surname** |  |
| **Institutional email address** |  |
| **Personal profile link** (optional) |  |
| **Position** (e.g. Research fellow) |  |
| **Principal affiliation (employer) including location** |  |
| **All other current professional affiliations** (if any) |  |
| **Substantive relevant past affiliations** (if any) |  |
| **Intended role in relation to CPRD** (e.g. data analyst) |  |
| **Qualifications** (degrees etc. with awarding body and year) |  |
| **ORCID** (please supply your ORCID if available) |  |
| **Direct experience of practicing in UK in primary care** | Yes / No |
| **Relevant expertise** (please indicate the nature of your expertise e.g. statistics, epidemiology, public health and for how long you have been working in the field) | |
| **Experience of using CPRD data** (indicate the number of CPRD studies in which you have personally been involved with and the number of resultant publications; if greater than 5, an exact number is not required) | |
| **Experience of using linked CPRD data** (indicate the number of linked data CPRD studies in which you have personally been involved with, provide details of which linkages have been used and the reference numbers of up to 5 relevant study protocols (use the most recent) | |
| **PMIDs** (Please supply up to 5 PMIDs PubMed IDs if available) | |