CONDITIONS OF ACCESS FOR THE CLINICAL PRACTICE RESEARCH DATALINK
School of Social and Community Medicine and CLAHRC West, University of Bristol

1. The Clinical Practice Research Datalink

The Clinical Practice Research Datalink (CPRD) contains sensitive confidential anonymised, longitudinal medical records of patients registered with contributing primary care practices across the UK. The CPRD database covers approximately 8.8% of the UK population, including practices in England, Northern Ireland, Scotland and Wales. As of September 2014, there are 684 GP practices and 13.58M acceptable (research quality) patients in CPRD, of which 5.69M are active (still alive and registered with the GP practice). Data has been collected from GP practices since 1987 and is updated monthly.

CPRD is a dynamic database whereby sensitive confidential data is collected from contributing practices on a regular basis (either daily or 4-6 weekly) and at the end of each month we take a 'snapshot' of the database called the monthly CPRD database build.

The University of Bristol has signed a Risk Sharing Licence Agreement with CPRD which places the University under strict legal obligations. Under this Licence, researchers can request CPRD data through the School of Social and Community Medicine (SSCM), following approval of their application by the CPRD-Independent Scientific Advisory Committee (ISAC) and the review by RED of the terms and conditions of any external funding body which may provide funds for UoB staff/students to access CPRD data.

This document outlines the conditions of access for the CPRD data under this agreement.

2. Restrictions on the use of data

2.1. The investigator may only be given access or provided the data following the approval of the research protocol by the CPRD-ISAC and review and approval of any external funders' terms and conditions if applicable.

2.1.1. In the event that the external funder changes during the access period, RED should be informed so that the terms and conditions of the new funders can be reviewed.

2.2. The investigators and members of their research team can only use the data for the purposes set out in the protocol submitted and approved by CPRD-ISAC. Any additional use of the data will require a new approval from CPRD-ISAC.

2.3. The investigator or any member of the research team shall not use the data, whether on its own or in conjunction with other data, for:

2.3.1. identifying, contracting or targeting patients;

2.3.2. identifying primary care practitioners or primary care practices; or

2.3.3. studying the effectiveness of advertising campaigns or sales forces.

2.4. The investigator will only be provided the amount of data requested in the protocol submitted and approved by the CPRD-ISAC. A data specification will be agreed upon by the investigator and the fob holders prior to data extraction.

3. Data security

3.1. The investigator will maintain adequate security measures to prevent unauthorised use or copying of the data, in accordance with the University of Bristol information security policies (http://www.bris.ac.uk/infosec/policies/docs/).

3.1.1. In accordance with this, copies of the dataset kept in physical locations, including, but not limited to, the hard drive of SSCM computers, work laptops, memory sticks and DVDs, should be encrypted.

3.1.2. Copies of the dataset must not be kept in unencrypted personal laptops.

3.2. The investigators and members of their research team who have access to the CPRD data shall complete the mandatory information security training provided by the University of Bristol prior to accessing the data (http://www.bris.ac.uk/infosec/training/). Evidence of completion would be required by the CPRD administration prior to release of data.

3.3. The investigator shall ensure that reports, papers or statistical tables that are published or released to third parties as a result of use of the data cannot be used to identify patients, contributing medical practitioners or contributing primary care practices. All reports, papers or statistical tables should not contain raw CPRD data.

3.4. If the investigator discovers that there is information in the database that can be used to identify any individual, primary care practitioner or primary care practice, the investigator should inform the CPRD immediately in writing.

3.5**. The investigator shall not permit any third party to access or use the data.**

3.6. The investigator will ensure that only members of the research team have access to the data. The investigator shall not transfer the data to any person outside the immediate research team.

3.6.1. If a member of the research team is a non-UoB employee, they can use the data but only within the UoB infrastructure. They should not be provided with copies of the data for storage, processing or analysis outside of UoB.

3.7. Any transfer of data shall use 7-zip encryption and will only be done via: 1.) personal pick-up of the encrypted DVDs by the Principal Investigator, or; 2.) secure courier service to transfer encrypted DVDs.

3.8. The investigator shall notify the CPRD Administrator in SSCM of any breach in the data security involving the CPRD data.

3.9. The Principal Investigator is responsible for their team members' awareness and continuing compliance with this agreement.

4. Audit of research

4.1. The investigator shall allow CPRD or SSCM, upon reasonable notice, access to their files and equipment (personal computers, laptops, etc), place of work and to the research being undertaken using the CPRD data, to enable the auditor to assess whether the data is being undertaken in accordance with the terms and conditions of the CPRD-Risk Sharing Agreement and these conditions of access.

5. Publications

5.1. Under no circumstances should raw CPRD data be published.

5.2. The investigator shall ensure that CPRD is acknowledged in any publication arising from the use of the data by including the following statement in the paper:

"*This study is based in part on data from the Clinical Practice Research Datalink obtained under licence from the UK Medicines and Healthcare products Regulatory Agency. However, the interpretation and conclusions contained in this report are those of the author/s alone*".

5.3. The investigator shall send a copy of any publication arising from the use of the data to CPRD and to the CPRD Administrator within the School of Social and Community Medicine.

6. Breach of the conditions of access

6.1. If the investigator or members of the research team are found to be using the data for any purpose not authorised by the ISAC approval, their access to the data will be suspended immediately. They will be reported to CPRD and will be asked to destroy all copies of the data in their possession.

6.2. If the investigator or members of the research team commits any breach of data security provisions, their access to the data will be suspended immediately. They will be reported to both the CPRD and the Information Rights Officer of the University of Bristol (Matthew Morrison) and will be asked to destroy all copies of the data in their possession.

Under the Licence agreement with CPRD the University is also exposed to significant financial liability payable by the School if the terms and conditions of the CPRD licence are breached by the University of Bristol.

Declaration

I have read and understood the above terms and ensure I and my research team will comply with them.

Principal Investigator:

Name: _____

Position: _____

Address: _____

_____

UoB Email: _____

Signature & date: _____

UOB ORCA code: _____

UOB budget code _____